



# **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 2013**

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# GENETIC TECHNOLOGIES LIMITED

## QUARTERLY ACTIVITIES REPORT FOR THE QUARTER ENDED 31 DECEMBER 2013

### OPERATIONS

#### Financial summary

Total cash receipts from customers during the quarter ended 31 December 2013 were \$1.3 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™ in the December quarter continues to demonstrate growth and further expansion of the product in the US market. 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.

During the quarter under review, a total of \$4,000,000 was received by the Company under its Share Purchase Plan ("SPP"), before the payment of associated costs. At the issue price of \$0.072 per share, this resulted in the issue of 55,555,556 further ordinary shares in the Company. Also during the quarter, the Company drew down redeemable convertible notes generating \$5,627,462 (being the Australian dollar equivalent of USD 5,000,000), before the payment of associated costs (refer below for details).

#### BREVAGen™ breast cancer risk test

##### *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 test samples received in each of the subsequent ten quarters has increased. As announced on 8 January 2014, a record number of BREVAGen™ test samples were received during the quarter ended 31 December 2013. Total samples received during the quarter was 1,125, representing growth of more than 23% over the preceding September quarter (914 samples), reinforcing the continuing increasing trend in market traction.

A total of 3,041 BREVAGen™ test samples were received during the 2013 calendar year as compared to 801 samples received during the 2012 calendar year – a growth of 280% year-on-year.

The test samples received continue to come from a broad mix of US geographical sales territories, demonstrating the growing acceptance of the test across the wider market. Further, as a result of both increased test sample numbers and positive reimbursement changes since 1 January 2013, total sales revenue for the test received during the quarter under review increased by more than 50% as compared to the preceding September quarter.

##### *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 these changes, the Company now uses a Miscellaneous Code when submitting claims for reimbursement from insurers. As part of this transition, the list price for a BREVAGen™ test was increased to enable the Company to receive payment for aspects of the test that were not previously available under the code stack. Importantly, while the Company has not sought to increase the maximum out-of-pocket amount that a given patient is required to pay for a BREVAGen™ test under its "Patient Protection Program", the average total payment received from closed cases, including all write-offs and denials for non-coverage, has increased significantly, despite an increase in the number of denials.



## OPERATIONS (cont.)

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

On 6 December 2013, GTG announced that the BREVAGen™ test was featured in the online issue of *Cancer Prevention Research* Vol 6 (12): pp 1328 - 36 dated 5 December 2013. The publication profiles the cost-effectiveness of the BREVAGen™ test versus direct MRI screening for breast cancer risk. The study, entitled "Cost-effectiveness of a Genetic Test for Breast Cancer Risk," was a collaborative project between GTG and Archimedes Inc. of San Francisco, a healthcare modeling and analytics organization.

Based on the study, BREVAGen™ was most cost-effective when given to patients classified as having an intermediate lifetime risk of breast cancer. For patients with a risk of 16% to 28%, the test resulted in savings of 0.023 quality-adjusted life years (QALYs) per patient at a cost of \$163,264 per QALY. The cost-effectiveness of using the BREVAGen™ test for patients with an intermediate Gail risk score is similar to that of other recommended strategies, including annual MRI for patients with a lifetime risk of greater than 20% or BRCA 1/2 mutations. Importantly, the model showed that the BREVAGen™ test yields a 2.7% reduction in cancer deaths relative to the Gail score alone for patients with a lifetime risk of at least 10%.

### *Further validation studies supporting BREVAGen™*

The Company continues to actively progress research programs with leading international academic collaborators to confirm the utility of genomic risk assessment in other ethnic populations and to incorporate the full portfolio of currently known common breast cancer susceptibility variants into the BREVAGen™ test.

Validation of the expanded test is expected to be completed in early in calendar 2014, with validation of the test for other ethnic populations expected to be completed in the first half of the 2014 calendar year. New versions of the BREVAGen™ test will subsequently be launched and offered in the US market.

## 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 various parties. Since then, Settlement and License Agreements have been executed with Navigenics Inc., Hologic Inc., Eurofins STA Laboratories Inc., GeneSeek Inc. and 454 Life Sciences Corporation (and its affiliates).

On 24 December 2013, the Company reported that several significant cases now pending in the District of Delaware, including cases against Bristol Myers Squibb, Pfizer and Merial, have each been allocated to the same Judge. While they are still 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. During the quarter, the Company also announced that it had executed agreements with Reprogenetics LLC and Bio-Reference Laboratories, Inc.

### Other licensing activities

The Company's licensing activities in Europe continue to progress, with a legal action now under way in the Netherlands against Hendrix Genetics NV, where rulings by the Courts are expected to be received during the current quarter, and with other actions in Europe now being planned by GTG.

GTG also reported during the quarter that in each year since 2005 the Company has received an agreed license annuity fee of AUD 1 million from Genzyme Corporation in USA. As yet, this payment has not yet been received for 2013, and GTG is now considering its various legal options.



## 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™**

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. The Jacobson Entities will not be able to vote at the GTG shareholder meeting to consider the approval of the Agreement.

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. Each option will entitle GTG to acquire one ordinary share in ImmunAid at a price of \$1.35 per share at any time for three years from the date on which the options are granted. In consideration for the options granted to GTG by ImmunAid, GTG will pay ImmunAid an option fee of \$500,000, of which \$351,618 will be satisfied by the forgiveness of outstanding debts currently owed to GTG by ImmunAid. GTG will pay the remaining \$148,382 owed on the option fee in cash.

All of the transactions above are subject to the receipt by GTG of an acceptable independent valuation of the Company's 4,500,000 shares in ImmunAid and an accompanying independent expert's fairness report; the receipt of all necessary regulatory approvals; and the receipt of the approval of the Company's shareholders at an Extraordinary General Meeting to be convened as soon as practicable at which the Jacobson Entities will be unable to vote.

Assuming the transactions proceed as outlined above, the number of ordinary issued shares in GTG will fall by 12.7% from 597,926,082 to 521,988,582, 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 5.85% of the Company's then total issued capital and Dr. Jacobson will continue his current role for GTG as Vice President, Global Licensing and IP and also as CEO of ImmunAid Limited.

### **RareCollect™**

Discussions with companies interested in pursuing potential commercial collaborations are continuing.

### **Gtech International Resources Limited**

On 12 December 2013, the Company announced that its former Canadian-listed subsidiary, Gtech International Resources Limited ("Gtech") had completed its acquisition of Sydney-based company Simavita Holdings Limited ("Simavita Holdings"), as originally disclosed by GTG to the ASX on 30 July 2013. As part of the transaction, in which Simavita Holdings raised approximately \$14.3 million via the issue of approximately 34.9 million new shares at an issue price of A\$0.41 per share (before the payment of costs and the repayment of certain debts), Gtech changed its name to Simavita Limited ("Simavita").

The shares of Simavita commenced trading on the TSXV, under the trading symbol "SV", on 6 December 2013. On 9 December 2013, Simavita lodged documents with the ASX pursuant to which it will also seek a listing of CHES Depositary Interests ("CDIs") on the ASX. If accepted, the ASX code "SVA" has been reserved for the CDI listing.

## **OTHER COMMERCIAL ASSETS (cont.)**

### **Gtech International Resources Limited (cont.)**

Immediately following the completion of the acquisition, Genetic Technologies Limited held a total of 1,306,166 shares in Simavita, representing approximately 2.3% of that company's total issued capital. As a result of the transaction, Gtech was deconsolidated from the GTG Group and a number of changes have been made to the Board of that company to reflect the new ownership. Details of the Simavita business can be found at [www.simavita.com](http://www.simavita.com)

## **CORPORATE MATTERS**

### **Capital raising**

As mentioned in the Company's previous Activities Report, subsequent to the end of the 2013 financial year, GTG raised a total of \$6,500,000 via the issue of 90,277,778 ordinary shares at an issue price of \$0.072 per share. On 18 November 2013, the Company received a further \$500,000, before the payment of associated costs, from one of the Underwriters of the Company's Share Purchase Plan whose clients subscribed for a total of 6,944,444 shares at the same issue price of \$0.072 per share.

### **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. On 20 January 2014, further Notes with a face value of USD 500,000 were converted in return for which Ironridge received 550,581 American Depositary 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 4,250,000.

### **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. During this time, Mr. Thomas Howitt will continue in the role of Acting CEO in addition to his usual roles of CFO and Company Secretary.

### **Changes to the Board of Directors**

On 29 November 2013, following the conclusion of the Company's 2013 Annual General Meeting ("AGM") of shareholders, Prof. Ian McKenzie and Mr. Grahame Leonard AM were appointed as Directors of the Company. At the conclusion of the AGM, two former Directors, Mr. Tommaso Bonvino and Mr. Benjamin Silluzio, ceased to be Directors of the Company.

On 12 December 2013, Dr. Paul Kasian was appointed as a Director of the Company.

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

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THOMAS G. HOWITT  
*Chief Executive Officer (Acting)*

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

# 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 2013**

### Consolidated statement of cash flows

	Current quarter (December 2013) A\$	Year to date (six months) A\$
<b>Cash flows related to operating activities</b>		
1.1 Receipts from customers	<b>1,306,669</b>	<b>2,335,505</b>
1.2 Payments for (a) staff costs	<b>(1,889,379)</b>	<b>(3,784,372)</b>
(b) advertising and marketing	<b>(333,791)</b>	<b>(528,554)</b>
(c) research and development	-	-
(d) leased assets	-	-
(e) other working capital	<b>(1,931,646)</b>	<b>(3,339,525)</b>
1.3 Dividends received	-	-
1.4 Interest and items of a similar nature received	<b>21,074</b>	<b>30,774</b>
1.5 Interest and other costs of finance paid	<b>(14,478)</b>	<b>(25,933)</b>
1.6 Income taxes paid	-	-
1.7 Grant and other income	-	-
<b>Net operating cash flows</b>	<b>(2,841,551)</b>	<b>(5,312,105)</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 (December 2013) A\$	Year to date (six months) A\$
1.8	Net operating cash flows (carried forward)	<b>(2,841,551)</b>	<b>(5,312,105)</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>(12,454)</b>	<b>(15,285)</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>(33,662)</b>	<b>(93,739)</b>
	<b>Net investing cash flows</b>	<b>(46,116)</b>	<b>(109,024)</b>
<b>1.14</b>	<b>Total operating and investing cash flows</b>	<b>(2,887,667)</b>	<b>(5,421,129)</b>
<b>Cash flows related to financing activities</b>			
1.15	Net proceeds from the issue of shares	<b>3,732,940</b>	<b>6,366,226</b>
1.16	Equity transaction costs	-	-
1.17	Net proceeds from borrowings	<b>5,565,181</b>	<b>5,565,181</b>
1.18	Advances to third parties	<b>(470)</b>	<b>(20,470)</b>
1.19	Dividends paid	-	-
1.20	Repayment of finance lease principal	-	-
	<b>Net financing cash flows</b>	<b>9,297,651</b>	<b>11,910,937</b>
	<b>Net increase / (decrease) in cash held</b>	<b>6,409,984</b>	<b>6,489,808</b>
1.21	Cash at beginning of quarter / year to date	<b>1,803,660</b>	<b>1,721,293</b>
1.22	Exchange rate adjustments	<b>2,703</b>	<b>5,246</b>
1.23	<b>Cash at end of quarter</b>	<b>8,216,347</b>	<b>8,216,347</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>99,427</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 \$74,556 paid to Directors during the quarter in respect of fees and superannuation. The amount also includes \$24,871 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	-	-

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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:

	Current quarter (December 2013) \$A	Previous quarter (September 2013) \$A
4.1 Cash on hand and at bank	<b>2,716,347</b>	<b>1,803,660</b>
4.2 Term deposits	<b>5,500,000</b>	-
4.3 Bank overdraft	-	-
4.4 Commercial Bills of Exchange	-	-
<b>Total cash at end of quarter (item 1.23)</b>	<b>8,216,347</b>	<b>1,803,660</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>Gtech International Resources Limited</b>
5.2 Place of incorporation or registration		<b>Yukon Territory, Canada</b>
5.3 Consideration for acquisition or disposal		<b>\$nil</b>
5.4 Total net liabilities		<b>\$9,172</b>
5.5 Nature of business		<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 January 2014**  
*Chief Executive Officer (Acting)*

Print name: **Thomas G. Howitt**

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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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