



# 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 2014**

# GENETIC TECHNOLOGIES LIMITED

## QUARTERLY ACTIVITIES REPORT FOR THE QUARTER ENDED 30 JUNE 2014

**Melbourne, Australia; 31 July 2014:** Molecular Diagnostics company Genetic Technologies Limited (ASX: GTG; NASDAQ: GENE) is pleased to announce the return to growth in BREVAGen™ test samples received during the quarter ended 30 June 2014. Total patient samples received during the quarter were **1,096**, representing 37% growth over the March 2014 quarter (800 samples). Domestic testing revenues, for the same period continued to exceed budget expectations.

### OPERATIONS

#### Financial summary

Total cash receipts from customers during the quarter ended 30 June 2014 were \$1.1 million taking the equivalent figure to \$4.8 million for the full 2014 financial year ended on that date.

Domestic testing revenues for the quarter under review continue to exceed budget expectations, while revenue generated by the Company's flagship test BREVAGen grew by 81% over the preceding March quarter. At June 30 2014 balance date, the company moved from cash to an accrual basis for recording revenue generated from the sale of the BREVAGen test product. This change resulted in a one-off upward adjustment to revenue of \$416k.

#### BREVAGen™ breast cancer risk test

*Test samples received for the full year to date:*

The start of CY14 brought with it severe winter weather conditions across large tracts of the US and this restricted patient and physician physical access to medical centres and willingness to attend for anything other than urgent medical care. Further to this challenge, the holiday period coincided with the introduction of the Affordable Care Act, so-called ObamaCare, which created uncertainty in patients' understanding of their out-of-pocket expense liability that also restricted the uptake of BREVAGen. With these factors removed, we saw a return of patients to doctors' offices and improved preparedness to take preventative care decisions.

The June quarter completes the 2014 financial year for GTG, with 3,935 samples received in the financial year, more than double that received in the previous corresponding period.

GTG benefited during the quarter from an increased focus on breast centres, radiology groups and high-population, health-conscious territories, and this continued focused activity is anticipated to result in further growth over the coming quarters.

The launch of the next generation BREVAGen, "BREVAGen Plus" later this calendar year, is anticipated to result in accelerated sample test volume growth.

#### *New Product Development:*

Planning is well progressed and GTG is on target to release "BREVAGen Plus" in Q4, CY14. The new version of BREVAGen incorporates an expanded SNP (Single Nucleotide Polymorphism) panel, providing an increase in the predictive power of the test. Importantly, it will also be validated in Hispanic and African American women populations, thereby increasing the applicable market and simplifying the marketing process for BREVAGen in clinics and breast centres.



## **OPERATIONS - BREVAGen™ breast cancer risk test (cont.)**

### *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 above change 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 increasing the time taken to receive reimbursement.

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

Further to the publication in the journal of *Cancer Prevention Research* Vol 6 (12), dated 5 December 2013: pp 1328–36, demonstrating the cost effectiveness of the BREVAGen test to guide MRI screening, 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 US payers of \$50,000 per quality-adjusted life year (QALY) saved.

Clinical utility studies are currently being designed and will be commenced 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**

GTG is asserting actions against a number of different companies in 4 different States in the U.S.

On 24 December 2013, GTG reported that efficiencies in both legal resources and court times have been achieved by consolidating 4 cases, pending in the district of Delaware, in front of the same judge. The consolidation includes significant cases against companies such as Bristol Myers Squibb and Pfizer. These cases are awaiting scheduling orders but have been deferred until the court has ruled on 2 pending invalidity motions brought by 3 of the parties in September 2013 and in February 2014.



### **LICENSING AND IP - Non-coding Assertion Program (cont.)**

On 12 March 2014, GTG announced that a further consolidation had been achieved in the Northern District of California where, following the transfer of the Natera case, it has been consolidated, for at least some of the proceeding with the Agilent case. Following the court's ruling in favour of GTG, - denying the motion to dismiss based on invalidity, issued on 9 March 2014 - case scheduling and discovery procedures are underway.

In the Glaxo-SmithKline LLC ("GSK") case in the District of North Carolina, GTG has filed a second amended complaint introducing infringement activities related to a second GTG patent. Subsequently, GSK has filed a motion to dismiss based on the familiar invalidity arguments raised by other parties. Further court activities will again be deferred until the ruling of the Judge in this matter.

### **Other licensing activities**

There are no updates to report relating to the remaining U.S or European cases.

### **OTHER COMMERCIAL ASSETS**

As part of GTG'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, GTG 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, when 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.

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.



## **OTHER COMMERCIAL ASSETS - ImmunAid™ (cont.)**

On 16 May 2014, GTG announced the completion of Share transactions with Dr Mervyn Jacobson, at which time, the then number of ordinary issued shares in GTG was reduced by 11.4%, from 664,769,002 to 588,831,502, following the cancellation of the shares acquired from the Jacobson Entities. Following the transaction, the Jacobson Entities were left with a total holding of 30,536,184 ordinary shares in GTG, representing 5.19% of the Company's then total issued capital.

## **CORPORATE MATTERS**

### **Convertible Notes**

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

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

As at 31 March 2014, Notes with a face value of USD 2,250,000 had been converted in return for which Ironridge has received 74,645,781 ordinary shares in GTG (including ordinary shares issued in lieu of interest payment). During the current quarter, further Notes with a face value of USD 1,000,000 were converted in return for which Ironridge received 42,516,090 ordinary shares (including ordinary shares issued in lieu of interest payment and an interest true-up adjustment). On 7 July 2014, Notes with a face value of USD 500,000 were converted in return for which Ironridge received 23,227,950 ordinary shares (including ordinary shares issued in lieu of interest payment). As a result of the above conversions, the face value of Notes remaining is reduced to USD 1,250,000.

### **Executive Moves and Appointments**

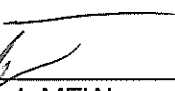
As previously announced, the Company is pleased to confirm:

1. The return of Ms. Alison Mew to full-time work to resume her position of Chief Executive Officer, as from Tuesday, 1 April 2014; and
2. The appointment of Mr Eutillio Buccilli as Chief Financial Officer, effective 2 June 2014.

With Eutillio's appointment, Acting Chief Financial Officer Ms. Bronwyn Christie relinquished this role on Friday, 30 May 2014 and thereby resumes her role of Financial Controller for the GTG Group while retaining the role of Company Secretary.

The Company wishes to thank Ms. Christie for her service and contribution during this time.

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

  
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ALISON J. MEW  
Chief Executive Officer

Dated this 31<sup>st</sup> day of July, 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")

**30 JUNE 2014**

### Consolidated statement of cash flows

	Current quarter (June 2014) A\$	Year to date (twelve months) A\$
<b>Cash flows related to operating activities</b>		
1.1 Receipts from customers	1,056,521	4,755,702
1.2 Payments for (a) staff costs	(1,994,629)	(7,801,333)
(b) advertising and marketing	(314,909)	(1,082,448)
(c) research and development	(31,866)	(31,866)
(d) leased assets	-	-
(e) other working capital	(1,515,416)	(6,371,584)
1.3 Dividends received	-	-
1.4 Interest and items of a similar nature received	43,359	116,047
1.5 Interest and other costs of finance paid	(12,778)	(52,550)
1.6 Income taxes paid	-	-
1.7 Grant and other income	190,395	190,395
<b>Net operating cash flows</b>	<b>(2,579,323)</b>	<b>(10,277,637)</b>

+ See chapter 19 for defined terms.

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

	Current quarter (June 2014) A\$	Year to date (twelve months) A\$
1.8 Net operating cash flows (carried forward)	(2,579,323)	(10,277,637)
<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	(20,804)	(47,917)
e) other non-current assets	(114,159)	(114,159)
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	-	-
f) other assets	577,497	577,497
1.11 Loans to other entities	-	-
1.12 Loans repaid by other entities (refer note below)	-	-
1.13 Other (provide details if material)	-	(183,011)
<b>Net investing cash flows</b>	<b>442,534</b>	<b>(232,410)</b>
<b>1.14 Total operating and investing cash flows</b>	<b>(2,136,789)</b>	<b>(10,045,227)</b>
<b>Cash flows related to financing activities</b>		
1.15 Net proceeds from the issue of shares	(21,282)	6,341,502
1.16 Equity transaction costs	-	-
1.17 Net proceeds from borrowings	-	4,827,532
1.18 Advances to third parties	-	-
1.19 Dividends paid	-	-
1.20 Repayment of finance lease principal	-	-
<b>Net financing cash flows</b>	<b>(21,282)</b>	<b>11,169,034</b>
<b>Net increase / (decrease) in cash held</b>	<b>(2,158,071)</b>	<b>1,123,807</b>
1.21 Cash at beginning of quarter / year to date	4,993,347	1,721,293
1.22 Exchange rate adjustments	(4,191)	(14,015)
1.23 <b>Cash at end of quarter</b>	<b>2,831,085</b>	<b>2,831,085</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	119,882
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 \$82,382 paid to Directors during the quarter in respect of fees and superannuation. The amount also includes \$37,500 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**

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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:

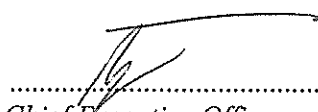
	Current quarter (June 2014) \$A	Previous quarter (March 2014) \$A
4.1 Cash on hand and at bank	2,831,085	1,743,347
4.2 Term deposits	-	3,250,000
4.3 Bank overdraft	-	-
4.4 Commercial Bills of Exchange	-	-
<b>Total cash at end of quarter (item 1.23)</b>	<b>2,831,085</b>	<b>4,993,347</b>

**Acquisitions and disposals of business entities**

	Acquisitions (Item 1.9(a))	Disposals (Item 1.10(a))
5.1 Name of entity	Not applicable	Gtech International Resources Limited
5.2 Place of incorporation or registration		Yukon Territory, Canada
5.3 Consideration for acquisition or disposal		\$nil
5.4 Total net liabilities		\$9,172
5.5 Nature of business		Dormant

**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: **31 July 2014**  
*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.