# 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 2015**

# GENETIC TECHNOLOGIES LIMITED

## QUARTERLY ACTIVITIES REPORT
## FOR THE QUARTER ENDED 31 March 2015

## Highlights

- Additional breast health centres to begin offering **BREVAGen*plus*®**
- Completed **$18.6M** capital raising
- Nasdaq deficiencies successfully remediated
- New research study supporting the use of **BREVAGen*plus*®** in breast cancer risk assessment

**Melbourne, Australia, 30 April 2015:** Molecular diagnostics company Genetic Technologies Limited (ASX: GTG; NASDAQ: GENE, "Company") is pleased to report that a further two (2) new breast health centres will begin to offer **BREVAGen*plus*®** to their at-risk patients in a systematic fashion. This is in addition to the six (6) breast health centres that the Company previously announced were set to adopt BREVAGen*plus*, of which all six (6) have in fact provided samples during the March 2015 quarter. In addition, the Company raised $18.6M from professional and sophisticated investors in the United States. The funds raised under the Financing will be used to support the Company's medium-term capital requirements and together with existing cash reserves, will support the Company's refocused US molecular diagnostics market and commercialisation of the Company's lead breast cancer risk test BREVAGen*plus.*

With an additional number of new breast health centres expected to follow suit later in calendar year 2015, the Company reiterates that it expects sales growth to accelerate in the second half of calendar 2015 and beyond.

Importantly, the Company believes that the adoption of BREVAGen*plus* by a total of eight (8) new breast health centres validates the company's recently re-focused sales and marketing strategy, announced in September 2014, whereby the Company shifted its focus to these large facilities. While these centres are more complex entities with longer sales cycles, they offer higher and more stable long-term revenue potential.

The Company is working closely with these pivotal breast health centres and referring health care practitioners to ensure the creation of a personalised comprehensive breast cancer risk assessment approach in which BREVAGen*plus* plays an integral role. In this way, the Company aims to reinforce the benefits of the test, ease its adoption by the new clinics and ensure its routine use by them.

By working with these breast health centres and health care practitioners, the Company has developed a protocol where women who may be at significant risk and have little to no family history of breast cancer, are being screened. Pilot programs have been instituted which essentially create a "safety net" for their patients, by assessing both hereditary as well as sporadic breast cancer risk.

Genetic Technologies Limited CEO Mr. Eutillio Buccilli added "This significantly changes the landscape; the paradigm shifts from detection and intervention to risk assessment, prevention and even earlier detection".

In October 2014, the Company announced the US release of BREVAGen*plus*, an easy-to-use predictive risk test for the millions of women at risk of developing sporadic, or non-hereditary, breast cancer, representing a marked enhancement in accuracy and broader patient applicability, over the Company's first generation BREVAGen™ product. Results from BREVAGen*plus* provide physicians with valuable information to assist in developing a patient-specific Breast Cancer Risk Reduction and Screening Plan based on professional medical society guidelines, such as the American Cancer

Society (ACS) (www.cancer.org) and The National Comprehensive Cancer Network (NCCN) (www.nccn.org).

Clinical support for BREVAGen*plus* was further enhanced with the release of findings from a new research study show that adding a panel of 77 single-nucleotide polymorphisms ("SNPs") improves the predictive accuracy of four commonly used breast cancer risk assessment models. This same panel of 77 SNPs is used in the Company's recently released BREVAGen*plus.* Results of the study were presented at the 2014 San Antonio Breast Cancer Symposium, on December 13, 2014.

For the March 2015 quarter, **512** BREVAGen*plus* test samples were received (YTD **2,233** BREVAGen/BREVAGen*plus* test samples received).

Prior to the release of BREVAGen*plus*, the Company revised its sales strategy to focus on large comprehensive breast treatment and imaging centres, in concert with its ongoing approach to independent physician and women's healthcare providers. This recent pivotal change of sales and marketing emphasis towards large breast health centres, which are more complex entities with a longer sales cycle, but with higher potential, is expected to lead to significant acceleration in growth and less volatile test volumes than the Company has experienced to date. However, this revised sales model involving the promotion of BREVAGen*plus* to comprehensive breast imaging and breast health centres, has resulted in a plateau in sales uptake and growth during this interim transition period. Sales growth is expected to accelerate as this transition is completed and these new breast health centres, with their attendant large number of at-risk and appropriate patients adopt BREVAGen*plus*.

## OPERATIONS

### Financial summary

Total cash receipts from customers during the quarter ended 31 March 2015 were $0.4 million, taking the equivalent figure to $2.1 million for the nine (9) months to date (previous corresponding period: $3.7 million). This corresponding period revenue includes revenue generated from the Australian heritage business that was divested on 19 November 2014.

### BREVAGen*plus* breast cancer risk test

*Test Samples received for the March quarter:*

For the March 2015 quarter, **512** BREVAGen*plus* test samples were received, (YTD **2,233** BREVAGen/BREVAGen*plus* test samples received). The revised sales model involving the promotion of BREVAGen*plus* to comprehensive breast imaging and breast health centres, has resulted in a plateau in sales uptake and growth during this interim transition period. Sales growth is expected to accelerate as this transition is completed and these new breast health centres, with their attendant large number of at-risk and appropriate patients adopt BREVAGen*plus*.

*Reimbursement:*

Up until the end of the 2012 calendar year, 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 changes the Company now uses a miscellaneous code when submitting claims for reimbursement from insurers. As part of this transition, the list price for the 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, notwithstanding this, the Company did not seek 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."

Though the Company's reimbursement per test (including write-offs and denials for non-coverage) has increased by more than 30%, the use of a miscellaneous code requires more administration and time by the Insurance Company to adjudicate and process the claim, 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, the Company 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 the Company and Archimedes Inc. of San Francisco, a healthcare modelling and analytics organisation. The study examined the cost-effectiveness of utilising BREVAGen to direct tamoxifen chemoprevention.

An in-silico (computer) 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 (1.20-1.66%, 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 saved.

Clinical utility studies have been designed and are currently proceeding through the Institutional Review Board process at a US breast cancer research institute. The data obtained from these studies will be utilised in direct contracting discussions with insurers and self-insured employer groups.

## LICENSING AND IP

### Non-Coding Assertion Program

As reported previously, on the 30 October 2014, Judge Stark issued a Memorandum Opinion finding Claim 1 of GTG's foundation '179 patent ineligible and granted the Motion to Dismiss. Legal Counsel has now prepared an appeal to the decision in the Federal Circuit. It is anticipated that the appeal will be argued in September 2015, with a decision being issued between December 2015 and June 2016. Counsel sought and achieved a stay of all non-appealed actions pending resolution of the Appeal. Several of those cases are asserted against major pharmaceutical companies.

If the appeal is successful in overturning Judge Stark's decision, the pending cases will be resumed and these U.S. licensing activities will proceed.

## 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 co-develop other assets and technologies in which the Group has an interest.

## CORPORATE MATTERS

### Notice and Results of Extraordinary General Meeting

On 4 February 2015, the Company released the Notice for an Extraordinary General Meeting of shareholders that was subsequently held at 10.00 am on Friday, 6 March 2015, at the Company's offices located at 60-66 Hanover Street, Fitzroy Victoria 3065. Shareholders were asked to consider and, if thought fit, to pass four (4) resolutions.

All four (4) resolutions that were put before the shareholders were passed on a show of hands.

### NASDAQ Notices

On 3 September 2014, the Company announced that it received a letter dated 29 August 2014, from the NASDAQ Stock Market, notifying the Company that for the last 30 consecutive business days, prior to 28 August, the bid price for the Company's common stock (ADRs), listed on the Nasdaq Stock Market, had closed below the minimum USD 1.00 per share requirement for continued inclusion under NASDAQ Marketplace Listing Rules.

This letter stated that, in accordance with the Listing Rules, the Company had 180 calendar days, or until 25 February 2015, to regain compliance.

To regain compliance, the Company undertook a reverse stock split (consolidation) which, when actioned, has the effect of resetting the existing ratio of 1 ADR representing 30 Ordinary shares to 1 ADR representing 150 Ordinary shares. The target date for the ratio change was Monday 19 January, 2015. From January 20 to February 2, 2015, the closing bid price of the Company's common stock has been at USD 1.00 per share or greater. Accordingly, the Company has regained compliance with Listing Rule 5550(a)(2), and as notified by Nasdaq on 4 February 2015, this matter is now closed.

On 6 November 2014, the Company announced that it had also received a letter dated 5 November 2014, from the Nasdaq Stock Market notifying the Company that, companies listed on the Nasdaq Capital market are required to maintain a minimum of USD 2.5 million in stockholder' equity for continued listing. Since the Company's Form 20-F, for the fiscal year ended June 30 2014, reported stockholders' equity of approximately USD 1.7 million, the Company does not meet the alternatives of market value of listed securities or net income from continuing operations, the Company no longer complies with the Nasdaq Marketplace Listing Rules (the "Rules").

The letter stated that in accordance with the Rules the Company has 45 calendar days, or until 22 December 2014, to submit a plan to regain compliance. If the plan is accepted, Nasdaq can grant the Company an extension of up to 180 calendar days from November 5, 2014 to evidence compliance.

On 28 January 2015, the Company received a letter from Nasdaq, dated 27 January 2015, advising that it had been granted an extension of time (on or before May 4, 2015) to regain compliance with the minimum stockholders' equity requirement.

Note that these rules only apply to the Company's common stock trading on the Nasdaq Capital Market and not the Company's share trading on the Australian Securities Exchange, the Company's home exchange.

**Financing**

On 15 September 2014, the Company announced plans to restructure and realign its group activities. The changes proposed would enable the Company to focus its strategy on the U.S. molecular diagnostics market and commercialisation of the Company's lead breast cancer risk test BREVAGen. The aim being to provide investors with a focused molecular diagnostic company and refined US commercialisation strategy for BREVAGen, with a significantly reduced operating cost base.

In support of these plans, the Company finalised the raising of $2.15M via the issue of unlisted secured (debt) notes, with a face value of $1.00, to existing and new Australian institutional and wholesale investors during September 2014. The debt notes carried a 10.0% coupon rate, and as approved at the Annual General Meeting, held on 25 November 2014, became convertible notes, which can be converted into ordinary shares (at a 10.0% discount to the 5 day VWAP). The convertible notes also carry free attached options to purchase further shares in the Company.

As at 31 March 2015, $2,125,000 of the convertible notes, together with the capitalised interest, had been converted into 150,961,041 ordinary shares in the Company. As at the date of this report, there are $25,000 convertible notes still remaining to be converted.

On the 22 January 2015, the Company announced that it had entered into a A$24 million Standby Equity Placement Facility Agreement with the Kentgrove Capital Growth Fund, an investment fund managed by Kentgrove Capital Pty Ltd, a Melbourne-based investment and advisory firm, to strengthen the Company's funding position.

Under the Agreement, Kentgrove Capital may provide the Company with up to A$24 million of equity capital via placements over the next 24 months. Proceeds from the Facility will be used to fund the growth of the Company's flagship lead breast cancer risk test, BREVAGen*plus* and for general working capital.

Under the Agreement, the Company can determine whether or not it will request a subscription from Kentgrove Capital, can set the time period of the placements, the maximum amount of the placements and the minimum issue price. For each placement made via the Facility, shares will be issued at a 5% discount to a volume weighted average price (VWAP) over the placement time period.

At the date of this report, the Company has received $2,603,111 (before associated costs) via the issue of equity placements by Kentgrove Capital Growth Fund as part of the standby Equity Placement Facility Agreement.

The Company has also received $1,844,500 from the exercise of options to purchase more shares which were attached to the unlisted secure debt note issued in October 2014.

**Key Managerial Changes**

As announced on 26 February 2015, Mr. Eutillio Buccilli, was appointed Chief Executive officer of the Company following the resignation of Ms. Alison Mew which was effective 31 December 2014.

**Annual Report**

The Company published its Annual Report on 27 October 2014. The Annual Report is available on the company's website at www.gtglabs.com

**Signed on behalf of Genetic Technologies Limited**

Bronwyn Christie

Dated this 27th day of April, 2015

Bronwyn Christie
*Financial Controller and Company Secretary*

*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 | Quarter ended ("current quarter") |
|---|---|
| **17 009 212 328** | **31 MARCH 2015** |

### Consolidated statement of cash flows

| | | Current quarter (March 2015) A$ | Year to date (nine months) A$ |
|---|---|---|---|
| | **Cash flows related to operating activities** | | |
| 1.1 | Receipts from customers | **363,492** | **2,117,753** |
| 1.2 | Payments for (a) staff costs | **(1,254,290)** | **(5,109,258)** |
| | (b) advertising and marketing | **(167,117)** | **(698,883)** |
| | (c) research and development | **(55,225)** | |
| | (d) leased assets | **-** | **(252,731)** |
| | (e) other working capital | **(1,509,281)** | **-** |
| | | | **(4,477,882)** |
| 1.3 | Dividends received | **-** | **-** |
| 1.4 | Interest and items of a similar nature received | **13,169** | **29,067** |
| 1.5 | Interest and other costs of finance paid | **(7,034)** | **(29,998)** |
| 1.6 | Income taxes paid | **-** | **-** |
| 1.7 | Grant and other income | **-** | **-** |
| | **Net operating cash flows** | **(2,616,286)** | **(8,421,932)** |

+ See chapter 19 for defined terms.

## Consolidated statement of cash flows (cont.)

| | | Current quarter (March 2015) A$ | Year to date (nine months) A$ |
|---|---|---|---|
| 1.8 | Net operating cash flows (carried forward) | **(2,616,286)** | **(8,421,932)** |
| | **Cash flows related to investing activities** | | |
| 1.9 | Payment for the acquisition of: | | |
| | a) businesses (item 5) | - | - |
| | b) equity investments | - | - |
| | c) intellectual property | - | - |
| | d) physical non-current assets | **(10,013)** | **(162,280)** |
| | 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 | **3,818** | **57,094** |
| | e) joint venture interest | - | - |
| | f) other assets | - | **2,100,895** |
| 1.11 | Loans to other entities | - | - |
| 1.12 | Loans repaid by other entities (refer note below) | - | - |
| 1.13 | Other (provide details if material) | - | - |
| | **Net investing cash flows** | **(6,195)** | **1,995,709** |
| **1.14** | **Total operating and investing cash flows** | **(2,622,481)** | **(6,426,223)** |
| | **Cash flows related to financing activities** | | |
| 1.15 | Net proceeds from the issue of shares | **21,277,841** | **21,518,934** |
| 1.16 | Equity transaction costs | - | - |
| 1.17 | Net proceeds from borrowings | - | - |
| 1.18 | Net proceeds from the issue of unlisted secured debt notes | - | **1,999,500** |
| 1.19 | Dividends paid | - | - |
| | **Net financing cash flows** | **21,277,841** | **23,518,434** |
| | **Net increase / (decrease) in cash held** | **18,655,360** | **17,092,211** |
| 1.20 | Cash at beginning of quarter / year to date | **1,274,808** | **2,831,085** |
| 1.21 | Exchange rate adjustments | **246,282** | **253,154** |
| 1.22 | **Cash at end of quarter** | **20,176,450** | **20,176,450** |

+ 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 |
|---|---|---|
| 1.23 | Aggregate amount of payments to the parties included in item 1.2 | **77,677** |
| 1.24 | Aggregate amount of loans to the parties included in item 1.11 | - |

1.25 Explanation necessary for an understanding of the transactions

**The amount included at Item 1.23 includes $77,677 paid to Directors during the quarter in respect of fees and superannuation.**

## 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<br>Hire purchase facility | - | - |

+ See chapter 19 for defined terms.

## 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 (March 2015) $A | Previous quarter (December 2014) $A |
|---|---|---|---|
| 4.1 | Cash on hand and at bank | **20,176,450** | **1,274,808** |
| 4.2 | Term deposits | - | - |
| 4.3 | Bank overdraft | - | - |
| 4.4 | Commercial Bills of Exchange | - | - |
| | **Total cash at end of quarter** (item 1.23) | **20,176,450** | **1,274,808** |

## Acquisitions and disposals of business entities

| | | Acquisitions *(Item 1.9(a))* | Disposals *(Item 1.10(a))* |
|---|---|---|---|
| 5.1 | Name of entity | **Not applicable** | **Not applicable** |
| 5.2 | Place of incorporation or registration | | |
| 5.3 | Consideration for acquisition or disposal | | |
| 5.4 | Total net liabilities | | |
| 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: Bronwyn Christie ..... Date: **27 April 2015**
*Financial Controller and Company Secretary*

Print name: **Bronwyn Christie**

+ 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.