# 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 September 2012**

# GENETIC TECHNOLOGIES LIMITED

## QUARTERLY ACTIVITIES REPORT
## FOR THE QUARTER ENDED 30 SEPTEMBER 2012

### OPERATIONS

### Financial summary

Total cash receipts from customers during the quarter ended 30 September 2012 were $1.19 million. Subsequent to the end of the quarter, the Company received a further $950,000 in net annuity payments in respect of a license that had been granted in previous years, together with $459,000 resulting from the exercise of 10.2 million options and fees arising from the granting of a license to One Lambda Inc.

Gross proceeds received during the quarter of $46,951 from the sale of equity investments were generated from the sale of 46,951 shares in former subsidiary ImmunAid Pty. Ltd. at a price of $1.00 per share. The Company still retains a 45.5% direct equity interest in ImmunAid Pty. Ltd.

At the end of the quarter, i.e. prior to the receipt of the above amounts after 30 September 2012, the Company's cash reserves stood at $6.7 million.

### BREVAGen™ breast cancer risk test

*Expansion into California and Florida, with New York to follow*

On 26 July 2012, the Company announced that the Laboratory Field Services Unit of the California Department of Public Health had granted a license to the Company's Australian-based laboratory allowing Genetic Technologies' U.S. subsidiary, Phenogen Sciences Inc., to offer Clinical Laboratory services to residents of California. On 25 September 2012, GTG announced that BREVAGen™ has been cleared for sale into the State of Florida following the grant of a permit to the Company's Australian-based laboratory by the Clinical Laboratory Unit of the Florida Agency for Healthcare Administration ("AHCA"). This effectively means that the BREVAGen™ test may now be offered for sale in the States of California and Florida which, together, represent between 15% and 20% of breast cancer incidence in the United States (based on breast cancer incidence rates: ACS Breast Cancer Facts & Figures 2011-12, ACS Cancer Facts & Figures 2012).

Following the Company's receipt of a certificate of compliance issued by the Centers for Medicare and Medicaid Services, the Company has submitted numerous applications for "Out of State Licensure," which allow BREVAGen™ to now also be sold in Pennsylvania, Rhode Island, Nevada, Tennessee, Maryland, California and now Florida. The Company has now 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. The New York State CLEP has confirmed lodgment of the Company's application with the assignment of the Provider Facility Identifier (PFI # 8705), and the application is in review. Once New York State approval is granted, the BREVAGen™ test will have been cleared for sale in all 50 U.S. States.

*Appointment of Mr. Mark Ostrowski*

On 13 September 2012, the Company announced the appointment of Mr. Mark Ostrowski as Senior Vice President Sales & Marketing Molecular Diagnostics. In this role, Mark is responsible for managing the U.S. sales effort for BREVAGen™. Mark brings to the Company over 20 years of sales and marketing experience in molecular diagnostics having served in senior managerial positions at companies focused on women's health and oncology, including as Director of Sales Operations at Myriad Genetics (NASDAQ: MYGN) and Director of Managed Care Services at DIANON Systems (NASDAQ: DIAN). Prior to joining GTG, Mark's career spanned both early stage and established biomedical companies. During his tenure at Myriad, he had comprehensive exposure to all aspects of sales and marketing, managing a sales force of over 200 representatives, demonstrating average annual revenue growth of over 50%, and generating new strategic divisions and best practice policies.

## OPERATIONS (cont.)

With the successful establishment of the Company's U.S. infrastructure over the past two and a half years, culminating in the launch of BREVAGen™, the Company is now sharpening the focus of the U.S. organization around sales and centralizing support activities in Australia. As a result, the leadership of the U.S. sales and marketing group has transitioned to Mr. Ostrowski. Mr. Lewis Stuart assisted the Company in a strategic advisory capacity during that process.

*CE marking in Europe*

On 8 August 2012, the Company announced that it had received European CE Mark approval for BREVAGen™. The CE Mark designation will enable BREVAGen™ to be sold in the EU and other countries that recognise the CE Mark. The initial commercial focus will be in the key markets of France and Germany. Breast cancer is the most common form of cancer in European women. In 2008, annual breast cancer incidence in the European Union (EU-27) was over 330,000. This is nearly double the incidence rate in the U.S. of just over 180,000 cases per year (cited electronically at http://globocan.iarc.fr/). Approximately 80% of women who develop breast cancer develop non-familial or sporadic breast cancer, that is, they have little or no family history of the disease.

*Conformité Européenne ("CE")*, meaning European conformity, is a mandatory conformity mark for certain products placed on market in the European Economic Area including medical devices and IVD tests. CE Marking ensures that the manufacturer's product conforms to the essential requirements of the relevant European health, safety and environmental protection legislation. IVD tests, in accordance with the EU directive 98/79/EC for IVDD, must be safe and function as per the manufacturer's intended purpose. BREVAGen's™ CE Marking certification was conducted by MT Promedt Consulting GmbH, a globally recognised European Authorized Representative with offices in Germany and the U.S.

*Other activities*

The Company has recently filed an application to Health Canada for licensure to sell the BREVAGen™ test into yet another unmet market. 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

The Company is progressing with its developmental work to increase the utility of the BREVAGen™ test through validating a number of recently identified breast cancer associated SNPs and their applicability in other ethnic populations. Expanding the currently available SNP panel will increase the predictive power of the test to provide even greater breast cancer risk data to physicians to better manage their patient's breast health plans.

The New York State Department of Health's Clinical Laboratory Evaluation Program (CLEP) has assigned Phenogen Sciences Inc. a Provider Facility Identity (PFI# 8705) and Project ID (# 31251), signifying the commencement of their review of the validation package submitted by the Company. In view of this submission, the Company is further bolstering its Quality Management System in accordance with CLEP compliance requirements.

## LICENSING AND IP

### Assertion programs

On 26 May 2011, the Company announced it had filed a third patent infringement law suit in the U.S., in the U.S. 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 Settlement and License Agreements have now been executed with Navigenics Inc., Hologic Inc., Eurofins STA Laboratories Inc. and GeneSeek Inc. and that settlement discussions with certain other parties to the Colorado suit are progressing.

### Other licensing activities

On 9 July 2012, the Company announced that it had expanded the scope and jurisdictional reach of its off balance sheet funded retention arrangement with Sheridan Ross P.C. ("Sheridan Ross") of Denver, Colorado. Originally limited to actions brought only in the U.S., and limited in scope to cover only the Company's 5,612,179, 5,851,762, 5,192,659 and 5,789,568 U.S. patents, the expanded assertion arrangement with Sheridan Ross now covers all of GTG's non-coding patents in all jurisdictions. Importantly, Sheridan Ross will now be able to assist GTG with asserting its non-coding patents globally, effectively acting as GTG's lead counsel in these international efforts, particularly in Europe.

On 6 September 2012, the Company announced that it had executed a license agreement with Conexio Genomics Pty. Ltd. of Fremantle, Western Australia. On 18 October 2012, the Company announced that it had also executed a covenant not to sue and release agreement with One Lambda Inc. of Canoga Park, California, U.S.A.

### Request for patent re-examination

On 9 July 2012, the Company announced that it had received formal notification from the United States Patent and Trademark Office ("USPTO") that it had received and granted a request for *ex parte* re-examination of claims 1-18 and 26-32 of the Company's 5,612,179 (the '179) non-coding DNA patent brought by Merial L.L.C. of Duluth, Georgia ("Merial").

Requesting re-examination is a common strategy employed by defendants in patent infringement proceedings and, as such, it is not unexpected from Merial who is currently a defendant in the above Colorado action brought by the Company for infringement of the '179 patent. The '179 patent is very robust having been through a previous re-examination with the USPTO which resulted in the re-issuing of the patent in full with all claims upheld. The Company firmly believes that the claims of the '179 patent will be upheld in the re-examination and, as was the case in previous challenges, GTG will actively defend this matter in order to have the claims reissued.

## OTHER COMMERCIAL ASSETS

As part of the Company's strategy to place a stronger emphasis on the expansion of its cancer diagnostic franchise, its research programs are being progressed with a view to out-license, co-develop or partner the respective technologies.

## OTTHER COMMERCAIL ASSETS (cont.)

### ImmunAid™

Following its successful $1 million capital raising in April 2012, the Company's former subsidiary ImmunAid Pty. Ltd. ("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 that company's intellectual property portfolio. GTG retains a 45.5% equity interest in ImmunAid.

### RareCellect™

Discussions with large international companies interested in pursuing potential commercial collaborations are continuing, with a number progressing due diligence on the RareCellect™ data and samples.

## CORPORATE MATTERS

On 24 July 2012, Mr. Greg Brown was appointed as a Director of the Company. Mr. Brown has over 25 years of international business experience in the healthcare industry and has held the role of Sales and Marketing Director for Baxter Diagnostics in Australia and in the UK; Senior Global Marketing Manager for Roche Molecular Systems; Vice President, Global Strategic Marketing for Digene Corporation; and has led sales, device management, marketing and managed care teams in Europe and the U.S. Most recently he held the role of Managing Director and CEO of diagnostics device company ImpediMed (ASX: IPD), which has a primary breast cancer focus. He remains on the board of ImpediMed as an Executive Director.

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 is to be held at **11.00 am** on **Tuesday, 27 November 2012** in the "Treetops" Room at Melbourne Museum. Copies of both documents can be found on the Company's website at www.gtglabs.com

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

**Signed on behalf of Genetic Technologies Limited**

Dated this 25th day of October, 2012

DR. PAUL D.R. MacLEMAN
*Chief Executive Officer*

*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** | **30 SEPTEMBER 2012** |

### Consolidated statement of cash flows

| | | Current quarter (September 2012) A$ | Year to date (three months) A$ |
|---|---|---|---|
| | **Cash flows related to operating activities** | | |
| 1.1 | Receipts from customers | **1,190,399** | **1,190,399** |
| 1.2 | Payments for (a) staff costs | **(1,858,325)** | **(1,858,325)** |
| | (b) advertising and marketing | **(202,780)** | **(202,780)** |
| | (c) research and development | **(19,797)** | **(19,797)** |
| | (d) leased assets | - | - |
| | (e) other working capital | **(1,364,242)** | **(1,364,242)** |
| 1.3 | Dividends received | - | - |
| 1.4 | Interest and items of a similar nature received | **87,019** | **87,019** |
| 1.5 | Interest and other costs of finance paid | **(9,932)** | **(9,932)** |
| 1.6 | Income taxes paid | - | - |
| 1.7 | Grant and other income | - | - |
| | **Net operating cash flows** | **(2,177,658)** | **(2,177,658)** |

+ See chapter 19 for defined terms.

## Consolidated statement of cash flows (cont.)

| | | Current quarter (September 2012) A$ | Year to date (three months) A$ |
|---|---|---|---|
| 1.8 | Net operating cash flows (carried forward) | **(2,177,658)** | **(2,177,658)** |
| | **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 | **(8,488)** | **(8,488)** |
| | e) other non-current assets | - | - |
| 1.10 | Proceeds from the disposal of: | | |
| | a) businesses (item 5) | - | - |
| | b) equity investments | **46,951** | **46,951** |
| | 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) | - | - |
| | **Net investing cash flows** | **38,463** | **38,463** |
| **1.14** | **Total operating and investing cash flows** | **(2,139,195)** | **(2,139,195)** |
| | **Cash flows related to financing activities** | | |
| 1.15 | Net proceeds from the issue of shares | - | - |
| 1.16 | Proceeds from sale of forfeited shares | - | - |
| 1.17 | Net proceeds from borrowings | - | - |
| 1.18 | Repayment of borrowings | - | - |
| 1.19 | Dividends paid | - | - |
| 1.20 | Repayment of finance lease principal | **(12,565)** | **(12,565)** |
| | **Net financing cash flows** | **(12,565)** | **(12,565)** |
| | **Net increase / (decrease) in cash held** | **(2,151,760)** | **(2,151,760)** |
| 1.21 | Cash at beginning of quarter / year to date | **8,900,235** | **8,900,235** |
| 1.22 | Exchange rate adjustments | **(5,254)** | **(5,254)** |
| 1.23 | **Cash at end of quarter** | **6,743,221** | **6,743,221** |

+ 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 | **93,621** |
| 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 $83,102 paid to Directors during the quarter in respect of fees and superannuation. The amount also includes $10,519 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<br>Hire purchase facility | **2,500,000** | **5,183** |

+ 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 (September 2012) $A | Previous quarter (June 2012) $A |
|---|---|---|---|
| 4.1 | Cash on hand and at bank | **1,085,547** | **2,380,114** |
| 4.2 | Term deposits | **5,657,674** | **6,520,121** |
| 4.3 | Bank overdraft | - | - |
| 4.4 | Commercial Bills of Exchange | - | - |
| | **Total cash at end of quarter** (item 1.23) | **6,743,221** | **8,900,235** |

## 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 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 October 2012**
*Chief Executive Officer*

Print name: **Dr. Paul D.R. MacLeman**

+ 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.