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 2015

GENETIC TECHNOLOGIES LIMITED

QUARTERLY ACTIVITIES REPORT
FOR THE QUARTER ENDED 31 December 2015

Highlights

- Published two new additional validation studies of **BREVAGen*plus*®**
- Benefited from American Cancer Society's changes to breast cancer screening guideline
- Continued to streamline operations and improve revenue margins
- Bolstered leadership team with the appointment of Chief Financial Officer
- Strengthened financial position, with shareholders voting in favour to refresh the Standby Equity Placement Facility with the Kentgrove Capital Growth Fund
- Maintained strong cash position with **AUD 14.5m** as at 31 December 2015

Melbourne, Australia, 27 January 2016: Molecular diagnostics company Genetic Technologies Limited (ASX: GTG; NASDAQ: GENE, "Company"), is pleased to provide its Quarterly Activities Report for the period ending 31 December 2015, together with the attached Appendix 4C.

"I'm especially pleased with the progress achieved this past quarter as we continue to amass scientific validation for the important role **BREVAGen*plus*®** plays in women's health and are making meaningful strides in the commercial development of this next generation predictive breast cancer test," commented Eutillio Buccilli, Chief Executive Officer of Genetic Technologies Limited.

A key accomplishment during the quarter was the publication of two new validation studies, which serve as a testament to the continued momentum for the Company's BREVAGen*plus* breast cancer risk assessment test in the scientific community.

On 21 December 2015, Genetic Technologies announced the publication of a paper entitled "Breast cancer risk prediction based on clinical models and 77 independent risk-associated SNPs in women aged under 50 years: Australian Breast Cancer Family Registry" in the peer-reviewed journal, Cancer, Epidemiology, Biomarkers and Prevention. The study was designed to examine the predictive accuracy of BREVAGen*plus* when using a variety of other breast cancer risk assessment methods and was conducted under the supervision of Professor John Hopper and first authored by Dr. Gillian Dite from the Centre for Molecular Epidemiology at The University of Melbourne. The authors utilised the Australian Breast Cancer Family Registry to conduct a case-control study of 1,155 women aged between 35 and 50 years. The authors concluded: "By combining a 77 SNP-based score with clinical models, the AUC (accuracy) for predicting breast cancer before age 50 years improved by >20%". The new risk prediction scores presented in the study, represent the strongest known means available for physicians to assess the risk of a woman developing breast cancer. The publication can be accessed at: http://cebp.aacrjournals.org/content/early/2015/12/16/1055-9965.EPI-15-0838.abstract.

BREVAGen*plus* combines genetic information with a common, questionnaire-based, method of breast cancer risk-assessment (termed the Breast Cancer Risk Assessment Tool (BRCAT) or Gail Score) to provide a more accurate estimate of a woman's risk of developing breast cancer. The genetic information used in BREVAGen*plus* is based on the presence/absence of 77 different single nucleotide polymorphisms (SNPs) in a woman's DNA, with each particular SNP being associated with breast cancer risk. While the presence or absence of each SNP has a small impact on breast cancer risk, collectively, the 77 SNPs can have a significant impact. The impact of the SNPs can move a patient up or down in terms of breast cancer risk classification, which as result, enables the most appropriate type/form of breast cancer screening available and may provide eligibility for prophylactic medications.

The finding that BREVAGen*plus* increases the predictive accuracy of breast cancer risk by greater than 20% is highly significant in the context of the healthcare system and of course, patient impact. On an annual basis, the economic burden associated with treating the later stages of breast cancer runs into the billions of dollars. By providing a more accurate assessment of breast cancer risk, detection can

occur earlier while the disease is still curable by straight forward surgery, which saves lives and reduces costs for all parties.

This publication comes on the back of the earlier study, validating the use of BREVAGen*plus* in African-American and Hispanic women in the U.S. The paper entitled "SNPs and Breast Cancer Risk Prediction for African-American and Hispanic Women" was published in the peer-reviewed journal, Breast Cancer Research and Treatment on 20 November 2015. The article can be reviewed at http://link.springer.com/article/10.1007/s10549-015-3641-7.

The study was first authored by Dr. Richard Allman in collaboration with an international team of experts in the field of cancer genetics that included Professor Charles Kooperberg, of The Fred Hutchinson Cancer Research Centre, Seattle, Professor Rowan Chlebowski, Medical Oncologist, Los Angeles Biomedical Research Institute at Harbor - UCLA Medical Centre and Dr. Ora Gordon, Director of Medical Genetics, Providence Medical Centre and Professor of Genetics, John Wayne Cancer Institute, California and Professor John Hopper of The University of Melbourne.

The authors studied 7,539 African-American and 3,363 Hispanic women from the Women's Health Initiative. The results from this study demonstrates that including information from the SNPs associated with breast cancer risk improves the discriminatory accuracy of BCRAT and IBIS for both African-American and Hispanic women. These groups of women comprise increasing proportions of the U.S. population and are both under-represented in scientific literature and the U.S. healthcare system. The results from this study are important to physicians in that it allows them to better target and develop individualised breast cancer prevention and screening strategies for more of their patients.

This publication is not only important because it increases the potential market for BREVAGen*plus* by about a third, but because it makes selling the test easier. The physician doesn't need to screen for race when deciding to offer a woman BREVAGen*plus* and advertising materials do not need to comment on the uncomfortable subject of racial applicability. BREVAGen*plus* is un-validated in Asians at this time.

These two recent publications are indicative of the Company's commitment to reinvigorate the pathway to peer-reviewed publications as it continues to execute on the initiative announced earlier in the year to improve upon the already existing scientific evidence base for BREVAGen*plus*.

The Company recognises that scientific and clinical study data are key drivers for test adoption by physicians and the major breast health centres and also for securing wider payer coverage. These two new publications provide compelling scientific evidence indicating that improved risk assessment has the potential to substantially lower the impact of breast cancer and supports the use of BREVAGen*plus* testing for African-American and Hispanic women. The next step for the Company is to confirm the potential health improvements in clinical studies, the first of which is scheduled to begin in Q3 FY16, with completion expected Q1 FY17. Two longer-term clinical trials are also expected to commence within the current financial year and are both designed to run for up to two years. One of the longer term studies will be prospective in design, looking at patient outcomes, with the other being retrospective, assessing the impact of the test on MRI screening rates. These studies combined are designed to inform the medical community of the measureable improvements in health outcomes associated with BREVAGen*plus* testing.

Scientific papers are the ultimate marketing material for medical device companies. Doctors and payers (health insurance companies, government, etc.) seek multiple points of confirmation that the device works as intended and leads to a meaningful improvement in women's health. Thus, the more papers that are published on BREVAGen*plus,* profiling its performance characteristics, the more certain doctors and payers will become to using and paying for the test.

Another important highlight that occurred during the quarter was The American Cancer Society's (ACS) recent changes to its breast cancer screening guideline which were published on October 20, 2015 in

the Journal of the American Medical Association. These guidelines, which are aimed at women with an average risk of breast cancer, raised the recommended age for first mammogram to 45 and suggested women over age 55 switch to biennial mammograms. However, the recommendations also create clinical ambiguity by concluding that women between ages 40 and 44 should still have the choice to get annual mammograms, and that women 55 years and older should likewise have the opportunity to continue annual screenings. BREVAGenplus, a clinically-validated, genetically-based breast cancer risk assessment test, can help physicians resolve this ambiguity by identifying which women, without a family history, still warrant earlier and/or more frequent screening.

The ACS' changes to its breast cancer screening guidelines, presents a challenge for physicians to identify who is appropriate for mammography screening before the age of 45 and annually after age 55. The BREVAGen*plus* test offers a solution, by providing physicians with a more accurate assessment of a patient's risk of developing sporadic breast cancer. This assessment can help guide physicians and patients as they develop a personalised breast cancer screening plan. More than 85 percent of women who are diagnosed with breast cancer have little or no family history of the disease and may have been overlooked for mammography screening prior to diagnosis. Therefore, it is critical that women understand the importance of knowing their own personal risk of developing sporadic, or non-hereditary breast cancer. BREVAGen*plus* is the only test of its kind that can help women and their doctors in this capacity.

The BREVAGen*plus* test assesses both clinical risk factors and genetic markers known to be associated with sporadic, or non-hereditary, breast cancer to determine a woman's five-year and lifetime risk of developing the disease. The test is designed to facilitate better informed decisions about breast cancer screening and preventative treatment plans for Caucasian, Hispanic and African-American women, age 35-65 years, who have not had breast cancer, lobular carcinoma in situ (LCIS) or ductal carcinoma in situ (DCIS), and have one or more risk factors for developing breast cancer.

OPERATIONS

Financial summary

For the quarter ended 31 December 2015, 284 BREVAGen/BREVAGen*plus* test samples were received, versus 344 tests received in the previous quarter (YTD - 628 tests samples received).

Total cash receipts from customers during the quarter ended 31 December 2015 were $0.3m (PCP: $0.7m), taking the equivalent figure to $0.6 for the half year ended on that date (PCP: $1.8m). Previous corresponding period revenue numbers include revenue generated from the Australian heritage business that was divested on 19 November 2014.

Operational cash spend for the December quarter was flat compared to the previous quarter. Based on the first half run rate, the annualised FY16 cash spend equates to $10.1m versus FY15: $13.2m and FY14: $15.2m, representing a reduction in annual cash spend of 23.5% and 33.6% respectively.

BREVAGen*plus* breast cancer risk test

In October 2014, the Company announced the U.S. 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, which represents a marked enhancement in accuracy and broader patient applicability over the Company's first generation BREVAGen product. The main enhancement in the test is the inclusion of 77 SNPs in the test panel compared to 7 for BREVAGen. BREVAGen*plus* is also validated for use in African American and Hispanic women, unlike its predecessor, which greatly expands the population of applicable women for the test. 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).

Prior to the release of BREVAGen*plus*, the Company revised its sales and marketing strategy to focus on large comprehensive breast treatment and imaging centres, in concert with its ongoing approach to serve independent physician and women's healthcare providers. Comprehensive breast centres are more complex entities with a longer sales cycle, however, they offer much higher and more stable long-term revenue potential.

The Company continues to work closely with these breast health centres and referring healthcare 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 routine usage.

Reimbursement:

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 methodology 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*plus* 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 insurance companies to adjudicate and process the claim, thus increasing the time taken to receive reimbursement.

Clinical utility studies and peer-review publications to drive reimbursement outcome:

As previously announced, the Company has launched an initiative to reinvigorate the pathway to Peer-Review Publication. Attaining such publications in medical journals will help to further strengthen the Company's commercial position and accelerate reimbursement discussions with private payers.

The Company had previously conducted multiple scientific studies to develop and validate the first generation BREVAGen test as well as created two health economic models to demonstrate potential cost savings and health benefits associated with the BREVAGen test. Importantly, due to the nature of the technology and the specific improvements incorporated in BREVAGen*plus*, the research undertaken and published based on the original version of the test remains applicable to the new and improved BREVAGen*plus* test.

Following is a list of peer-reviewed publications on the BREVAGen and BREVAGen*plus* tests, to date:

1) **"Breast cancer risk prediction based on clinical models and 77 independent risk-associated SNPs in women aged under 50 years: Australian Breast Cancer Family Registry."** *Cancer, Epidemiology, Biomarkers and Prevention. 2015 Dec 16, [Epub ahead of print].*

2) **"SNPs and Breast Cancer Risk Prediction for African-American and Hispanic Women"** *Breast Cancer Research & Treatment. 2015 Dec;154(3):583-9.*

3) "**Cost-effectiveness of a Genetic Test for Breast Cancer Risk**". *Cancer Prevention Research. 2013 Dec;6(12):1328-36.*

4) "**Economic Evaluation of Using a Genetic Test to Direct Breast Cancer Chemoprevention in White Women with a Previous Breast Biopsy**". *Applied Health Economics and Health Policy*. 2014 Apr;12(2):203-17.

5) "**Using SNP genotypes to improve the discrimination of a simple breast cancer risk prediction model**". Breast Cancer Res Treat. 2013 Jun;139(3):887-96.

6) "**Assessment of clinical validity of a breast cancer risk model combining genetic and clinical information**". J Natl Cancer Inst. 2010 Nov 3;102(21):1618-27.

And supporting presentations:

1) Dite GS, Allman R, Hopper JL. (2014). Value of adding Single-Nucleotide Polymorphism panel markers to phenotypic algorithms of Breast Cancer risk. Proceedings of the San Antonio Breast Cancer Symposium, December 2014.

2) Allman R, Dite GS, Hopper JL. (2015). Should women with a projected 5-year risk of developing breast cancer of 1.4% or higher be offered pharmacologic risk reduction? Proceedings of the World Congress on Controversies in Breast Cancer, October 2015.

3) Jacoby E, DiCicco, Allman R. (2013). Impact of genomics on the assessment and management of breast cancer risk in a women's healthcare clinic. Proceedings of the National Consortium of Breast Centres March 2013.

4) Fohlse HJ, Dinh TA, Allman R. (2013). Genetic testing for breast cancer risk estimation – A cost-effectiveness analysis. Presented at The California Pacific Medical Centre Breast Cancer Risk Assessment Workshop June 2013.

5) Fohlse HJ, Dinh TA, Allman R. (2013). Genetic testing for breast cancer risk estimation – A cost-effectiveness analysis. Presented at the San Antonio Breast Cancer Symposium December 2013.

LICENSING AND IP

The Company continued to bolster its intellectual property portfolio and on 6 August 2015, announced the issuance of U.S. Patent Nos: 9,051,617 and 9,068,229. These patents cover three core genetic markers referred to as SNPs in BREVAGen*plus*, and comprise an important part of the commercialisation strategy for the test. This patent family is assigned to Cambridge University, England and licensed exclusively to Genetic Technologies Limited. The particular SNPs in question were amongst the first of the breast cancer susceptibility loci to be consistently and robustly confirmed across multiple genome-wide association studies, such that their inclusion in BREVAGen*plus* provides the test with an additional significant proprietary competitive advantage over other SNP-based tests that might be developed.

Non-Coding Assertion Program

As reported previously, on the 30 October 2014, Judge Stark issued a Memorandum Opinion finding Claim 1 of the GTG's foundation '179 patent ineligible and granted that Motion to Dismiss. Legal Counsel prepared an appeal to the decision in the Federal Circuit. Counsel sought and achieved a stay of all non-appealed actions pending resolution of the Appeal.

On 7 December 2015, GTG argued before the Federal Circuit Court of Appeals in Washington DC that Claim 1 of the GTG's foundation '179 patent is patent eligible under the standards set forth in the Mayo/Alice line of Supreme Court cases, and that Judge Stark's decision to grant motions to dismiss finding Claim 1 patent ineligible should be reversed. It is anticipated that the Federal Circuit will issue its decision on the appeal between June and September 2016. If the appeal is successful in overturning Judge Stark's decision, the pending cases may be immediately resumed.

There are five cases pending, several of those cases are asserted against major pharmaceutical companies.

CORPORATE MATTERS

Notice and Results of 2015 Annual General Meeting

On 27 October 2015, the Company released the Notice for the 2015 Annual General Meeting of shareholders that was subsequently held at 10.30 am on Wednesday, 25 November 2015, at "Treetops", Melbourne Museum. All seven (7) resolutions that were presented to shareholders for voting, were passed.

Financial Stability and Growth Capital

On the 22 January 2015, the Company announced that it had entered into 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 Genetic Technologies with up to $24 million of equity capital via placements over the next 24 months. 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. As at the date of this report, the Company has received $2,603,111.00 (before associated costs) via the issue of equity placements by Kentgrove Capital Growth Fund as part of the Standby Equity Placement Facility Agreement.

Key Managerial Appointment

On 6 October 2015, the Company announced the appointment of Mr. Kevin Fischer as Chief Financial Officer and joint Company Secretary, effective 2 November 2015.

Annual Report

The Company published its Annual Report on 24 September 2015. The Annual Report is available on the Company's website at www.gtglabs.com

Signed on behalf of Genetic Technologies Limited

Date: 27 January, 2016

Eutillio Buccilli
Executive Director & 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	**31 December 2015**

Consolidated statement of cash flows

		Current quarter (December 2015) A$	Year to date A$
	Cash flows related to operating activities		
1.1	Receipts from customers	**254,375**	**608,160**
1.2	Payments for (a) staff costs	**(1,116,594)**	**(2,253,410)**
	(b) advertising and marketing	**(198,942)**	**(393,903)**
	(c) research and development	**(108,487)**	**(115,922)**
	(d) leased assets	-	-
	(e) other working capital	**(1,209,435)**	**(2,300,751)**
1.3	Dividends received	-	-
1.4	Interest and items of a similar nature received	**13,803**	**17,495**
1.5	Interest and other costs of finance paid	-	**(5,870)**
1.6	Income taxes paid	-	-
1.7	Grant and other income	-	-
	Net operating cash flows	**(2,365,280)**	**(4,444,201)**

+ See chapter 19 for defined terms.

Consolidated statement of cash flows (cont.)

		Current quarter (December 2015) A$	Year to date A$
1.8	Net operating cash flows (carried forward)	**(2,365,280)**	**(4,444,201)**
	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	**(103,024)**	**(263,698)**
	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		
	f) other assets	-	-
		-	-
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	**(103,024)**	**(263,698)**
1.14	**Total operating and investing cash flows**	**(2,468,304)**	**(4,707,899)**
	Cash flows related to financing activities		
1.15	Net proceeds from the issue of shares	-	**(1,654)**
1.16	Equity transaction costs	-	-
1.17	Net proceeds from borrowings	-	-
1.18	Net proceeds from the issue of unlisted secured debt notes	-	-
1.19	Dividends paid	-	-
	Net financing cash flows	**-**	**(1,654)**
	Net increase / (decrease) in cash held	**(2,468,304)**	**(4,709,553)**
1.20	Cash at beginning of quarter / year to date	**17,729,966**	**18,341,357**
1.21	Exchange rate adjustments	**(742,121)**	**887,737**
1.22	**Cash at end of quarter**	**14,519,541**	**14,519,541**

+ 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	**156,889**
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 $156,889 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		
	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 (December 2015) $A	Previous quarter (September 2015) $A
4.1	Cash on hand and at bank	**12,329,804**	**17,729,966**
4.2	Term deposits	2,189,737	-
4.3	Bank overdraft	-	-
4.4	Commercial Bills of Exchange	-	-
	Total cash at end of quarter (item 1.23)	**14,519,541**	**17,729,966**

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: ..... Date: **27 January 2016**
CFO/ Company Secretary

Print name: **Kevin Fischer**

+ 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.