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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 2016



HIGHLIGHTS

- Realigned and repositioned the BREVAGen^{plus}® test
- Exclusive worldwide license Agreement to develop Colorectal Cancer Risk assessment test
- Completed \$8.1M capital raising
- Strong cash position, with \$15.0M in cash

Melbourne, Australia, 27 January 2017: Genetic Technologies Limited (ASX: GTG; NASDAQ: GENE, “Company”), a molecular diagnostics company specialising in cancer genomics, and provider of BREVAGen^{plus}®, a first-in-class, clinically validated risk assessment test for sporadic breast cancer, is pleased to provide its Quarterly Activities Report for the period ending 31 December 2016, together with the attached Appendix 4C.

“The past quarter saw significant progress for the company on multiple fronts. In addition to executing on our ongoing commitment to continually improve the BREVAGen^{plus}’ product specifications, we enhanced our pipeline with a colorectal cancer asset, which represents a large market opportunity, and strengthened the balance sheet via a private placement to U.S. institutional investors,” commented Eutillio Buccilli, Executive Director and Chief Executive Officer of Genetic Technologies.

Operations

Financial snapshot

BREVAGen^{plus} test samples received for the quarter were 278, compared to 330 in the previous quarter (Q1 FY17), while 284 samples were received in the PCP (Q2 FY16). For the half year to date, 608 tests samples were received compared to 628 test received in the PCP.

Total cash receipts from customers during the quarter ended 31 December 2016 were \$184k, compared to \$178k in the previous quarter, taking the equivalent figure to \$362k for the half year ended on that date. The average revenue per test receipt achieved for the half year to date was 5% higher than that achieved over FY16.

Operational cash spend for the half year was \$4.1M, \$0.9M less than the previous corresponding half year period of \$5.0M. Based on the first half actual run rate, the annualised FY17 cash spend equates to \$8.2M versus FY16 of \$9.2M, representing a reduction in annual cash spend of 11%.

As at 31 December 2016, the Company had \$15.0M in cash.

BREVAGen^{plus} breast cancer risk test

Marketing Update

Subtle changes to the test will help drive market acceptance

An internal review conducted by the Company of the BREVAGen^{plus} test, revealed a number of changes that could be made to improve the underlying science base and the tests marketability. These changes have since been implemented. For instance, the clinical risk questionnaire utilised in BREVAGen^{plus} has been simplified from the current seven questions of the Gail Model to just two questions: “Age” and “Any First Degree Relatives.” Additionally, test results will be reported as a 5-year Absolute Risk of Developing Breast Cancer. This approach is modelled on that of Mavaddat et al (2015) 107(5): djv036 and provides multiple benefits. It simplifies the data-input requirement by the physician, aligns the product more firmly with U.S. clinical guidelines, in particular, the United States Preventative Services Task Force (USPSTF) recommendation statement on chemoprevention of breast cancer, and automatically strengthens the validation data by tying the test to a multinational study of approximately 80,000 women. Furthermore, by removing the reliance upon the Gail Model, the applicable age-range



Quarterly Activities Report for the quarter ended 31 December 2016

for the test can be extended to the lower age of 20 years old. However, given the product alignment with the USPSTF, the Company has decided to retain the current recommended age for patient testing at 35 years.

To accommodate the above changes, the Company redesigned the BREVAGen $plus$ algorithm relying upon U.S. Surveillance, Epidemiology, and End Results (SEER) data for breast cancer incidence and competing mortality to calculate absolute risk. The Company has also redesigned test reports and corresponding test request forms and revised its marketing material. To aid physician education, Genetic Technologies has prepared a white paper explaining and detailing these product enhancements.

Aligning the BREVAGen $plus$ test with professional guidelines clearly strengthens BREVAGen $plus$ ' role in personal healthcare management and, thus, represents a marked improvement in product positioning. Furthermore, existing Tamoxifen recommendation studies provide crystal clear 'clinical utility', with physicians now obligated to offer breast cancer risk assessment to their patients. The simplification of the test questionnaire is designed to enable physicians to easily incorporate BREVAGen $plus$ testing into their daily routine. A recent survey found that up to 76% of clinicians never calculate breast cancer risk, Cancer Detect Prev (2015) 31(5): 375-83, indicating that a sufficiently easy to perform test, like BREVAGen $plus$, would help physicians satisfy their obligation to the patient.

The enhanced test has been piloted with a national roll-out on schedule for late January 2017.

Clinical studies and peer-review publication update

The Company recognises that scientific papers represent the ultimate marketing material for BREVAGen $plus$ and that scientific and clinical study data are key drivers to further validate the test and strengthen its commercial position. Therefore, the support of peer-reviewed publications is instrumental in keeping both physicians and payers informed on scientific advancements and test improvements.

Alignment of the BREVAGen $plus$ test with the USPSTF recommendation statement on risk reduction automatically confers clinical utility as a means of adherence to that recommendation. In addition, a comprehensive manuscript, describing the scientific basis for the product change, supported by detailed statistical analysis of Gail model operation within the initial version of the BREVAGen $plus$ test, is in the final stages of preparation. The Company expects to submit the manuscript for publication in January 2017.

Given the realignment of the product to USPSTF guidelines on risk reduction, the output of two questionnaire-based clinical studies, which commenced in Q4 FY16, is being re-evaluated to ensure that we maintain our messaging alignment with those guidelines. The outcome of this re-evaluation may impact the decision to go to publication, or at the very least, focus our attention to only that data directly relevant to the guidelines. A third longer term prospective clinical study, examining patient outcomes based on a 5-year follow-up after BREVAGen $plus$ testing, is in the latter stage of development. It too will be specifically aligned with current guidelines.

While the Company continues to commit significant capital and resources to optimise BREVAGen $plus$, it is pleased to advise that it has received confirmation that AusIndustry has accepted and approved that the costs associated with recent overseas research activities are eligible for the R&D Tax Incentive, representing a 45% cash refund from the Australian Tax Office.

Colorectal cancer risk assessment test

On the 29 November 2016, Genetic Technologies announced the signing of an exclusive worldwide license agreement with The University of Melbourne for the development and commercialisation of a novel colorectal cancer (CRC) risk assessment test.

The core technology behind this test was developed by Professor Mark Jenkins and his research team at the University's Centre for Epidemiology and Biostatistics. Results from preliminary modelling studies



were first published online in *Future Oncology* on 1 February 2016, in a Paper entitled “*Quantifying the utility of single nucleotide polymorphisms to guide colorectal cancer screening*,” 2016 Feb: 12(4), 503-13. This simulated case-control study of 1 million patients indicated that a panel of 45 known susceptibility SNPs can stratify the population into clinically useful CRC risk categories. In practice, the technology could be used to identify people at high risk for CRC who should be subjected to intensive screening, ultimately reducing the risk of occurrence and death from the disease. Those identified as low risk of CRC can be spared expensive and invasive screening, thereby preventing adverse events and unjustified expenses. A scientific validation study supporting this work is nearing completion and is expected to be submitted for publication within the next four (4) months.

The fundamental technology is similar to the BREVAGen^{plus} test and will fit synergistically into the Company’s existing infrastructure and processes. The CRC test represents a significant milestone for the Company as it seeks to diversify its product pipeline and become a key player in the SNP-based cancer risk assessment landscape. The commercial development strategy for the CRC test will benefit from the BREVAGen^{plus} experience in the marketplace.

The terms and conditions of the Agreement are confidential; however, Genetic Technologies will be responsible for the commercial development of the test. In addition, as part of the Agreement, The University of Melbourne and Genetic Technologies have embarked on a robust, ongoing research collaboration enabling the Company to leverage the University’s renowned world-class expertise in SNP-based risk assessment and risk model development. The partnership with the University is comprehensive and highlights the Company’s overall corporate mission to become a leader in the cancer genomics focused diagnostics’ industry while enhancing its pipeline of risk assessment products.

Excluding skin cancers, CRC is the third most common cancer diagnosed in both men and women in the United States representing an overall lifetime risk of about 1 in 20 (5%). CRC is also the third leading cause of cancer-related deaths in the United States when men and women are considered separately, and the second leading cause when both are combined. As with breast cancer, early diagnosis is key as the majority of CRC cases are preventable by early detection and removal of precancerous polyps. According to the American Cancer Society, when diagnosed at an early stage (before the disease has spread outside the colon), the relative 5-year survival rate for CRC is 92% and 87% for rectal cancer, while the respective survival rate for late stage (metastatic) disease is much lower, at 11% and 12%, respectively. The main challenge with current CRC screening methodologies is compliance (the patient actually doing and completing the test), with the NCI stating that compliance in one of the large RCTs was ~47%, theoretically halving the impact of screening on CRC mortality.

The most common CRC screening tool is a faecal occult blood test (FOBT) or visual inspection of the bowel by endoscopy (Colonoscopy or Sigmoidoscopy). FOBT-based screening has been shown to reduce CRC mortality by three very large randomised controlled trials, according to the U.S. National Cancer Institute (NCI). FOBT screening has a fairly high sensitivity but low positive predictive value meaning a patient who returns a positive FOBT, then goes on to receive a diagnostic colonoscopy.

Colonoscopy may be used as a primary screening tool in certain patients, but the cost and the infrastructure required to use it as a primary tool are prohibitive. As with breast cancer, the more the physician can tailor a patient’s screening program to their level of risk of developing the disease, the greater impact screening will have. The development of a much improved CRC risk assessment tool has the potential to provide a significant health benefit by better targeting the existing screening modalities and improving compliance among those patients most at risk of developing CRC. Risk stratification would also likely influence the age a patient will start screening and the frequency.

Corporate Matters

Notice and Results of 2016 Annual General Meeting

On 24 October 2016, the Company released the Notice for the 2016 Annual General Meeting of shareholders that was subsequently held at 10.30 am on Wednesday, 23 November 2016, at “Treetops”, Melbourne Museum. All five (5) resolutions that were presented to shareholders for voting, were passed.



Quarterly Activities Report for the quarter ended 31 December 2016

Financing

On 6 December 2016, the Company raised \$8.1M (before transaction costs) from professional and sophisticated investors in the United States. The funds raised, together with existing cash reserves, will be used to facilitate the Company's expansion requirements in relation to BREVAGen^{plus}, the development and commercialisation of the colorectal cancer risk assessment test, and for general working capital purposes.

Signed on behalf of Genetic Technologies Limited

A handwritten signature in blue ink, appearing to read "Eutillio Buccilli", is written over a horizontal line.

Eutillio Buccilli
Executive Director and Chief Executive Officer

Date: 27 January, 2017

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Appendix 4C

Quarterly report for entities subject to Listing Rule 4.7B

Introduced 31/03/00 Amended 30/09/01, 24/10/05, 17/12/10, 01/09/16

Name of entity

GENETIC TECHNOLOGIES LIMITED

ABN

17 009 212 328

Quarter ended ("current quarter")

31 DECEMBER 2016

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	184	362
1.2 Payments for		
(a) research and development	(70)	(94)
(b) product manufacturing and operating costs	(56)	(172)
(c) advertising and marketing	(203)	(420)
(d) leased assets	-	-
(e) staff costs	(874)	(2,074)
(f) administration and corporate costs	(713)	(1,405)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	10	26
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(1,722)	(3,777)

2. Cash flows from investing activities

2.1 Payments to acquire:		
(a) property, plant and equipment	(5)	(19)
(b) businesses (see item 10)	-	-
(c) investments	-	-

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Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
(d) intellectual property	-	-
(e) other non-current assets	-	-
2.2 Proceeds from disposal of:		
(a) property, plant and equipment	49	49
(b) businesses (see item 10)	-	-
(c) investments	-	-
(d) intellectual property	-	-
(e) other non-current assets	-	-
2.3 Cash flows from loans to other entities	-	-
2.4 Dividends received (see note 3)	-	-
2.5 Other (provide details if material)	-	-
2.6 Net cash from / (used in) investing activities	44	30

3. Cash flows from financing activities		
3.1 Proceeds from issues of shares	8,050	8,050
3.2 Proceeds from issue of convertible notes	-	-
3.3 Proceeds from exercise of share options	-	-
3.4 Transaction costs related to issues of shares, convertible notes or options	(920)	(920)
3.5 Proceeds from borrowings	-	-
3.6 Repayment of borrowings	-	-
3.7 Transaction costs related to loans and borrowings	-	-
3.8 Dividends paid	-	-
3.9 Other (provide details if material)	-	-
3.10 Net cash from / (used in) financing activities	7,130	7,130

4. Net increase / (decrease) in cash and cash equivalents for the period		
4.1 Cash and cash equivalents at beginning of quarter/year to date	8,939	11,180
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(1,722)	(3,777)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	44	30
4.4 Net cash from / (used in) financing activities (item 3.10 above)	7,130	7,130

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Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
4.5	Effect of movement in exchange rates on cash held	611	439
4.6	Cash and cash equivalents at end of quarter	15,002	15,002

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	15,002	8,939
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	15,002	8,939

6. Payments to directors of the entity and their associates

- 6.1 Aggregate amount of payments to these parties included in item 1.2
- 6.2 Aggregate amount of cash flow from loans to these parties included in item 2.3
- 6.3 Include below any explanation necessary to understand the transactions included in items 6.1 and 6.2

Current quarter
\$A'000

157

-

The amount included at Items 6.1 & 6.2 include \$156,841 paid to Directors during the quarter in respect of fees and superannuation.

7. Payments to related entities of the entity and their associates

- 7.1 Aggregate amount of payments to these parties included in item 1.2
- 7.2 Aggregate amount of cash flow from loans to these parties included in item 2.3
- 7.3 Include below any explanation necessary to understand the transactions included in items 7.1 and 7.2

Current quarter
\$A'000

-

-

8. Financing facilities available <i>Add notes as necessary for an understanding of the position</i>	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
8.1 Loan facilities	-	-
8.2 Credit standby arrangements	-	-
8.3 Other (please specify) – Credit Card	317	38
8.4 Include below a description of each facility above, including the lender, interest rate and whether it is secured or unsecured. If any additional facilities have been entered into or are proposed to be entered into after quarter end, include details of those facilities as well.		

Credit card facilities:

1. Secured - Bank of America, \$167,000 facility with interest at 9.5% p.a.
2. Unsecured -National Australia Bank, \$150,000 facility with interest at 12.05% p.a.

9. Estimated cash outflows for next quarter	\$A'000
9.1 Research and development	139
9.2 Product manufacturing and operating costs	98
9.3 Advertising and marketing	389
9.4 Leased assets	-
9.5 Staff costs	1,198
9.6 Administration and corporate costs	815
9.7 Other (provide details if material) – Plant & Equipment	189
9.8 Total estimated cash outflows	2,828

10. Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)	Acquisitions	Disposals
10.1 Name of entity	-	-
10.2 Place of incorporation or registration	-	-
10.3 Consideration for acquisition or disposal	-	-
10.4 Total net assets	-	-
10.5 Nature of business	-	-

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Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.



Sign here:
Company secretary

Date: 27 January 2017

Print name: Kevin Fischer

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 that wishes to disclose additional information is encouraged to do so, in a note or notes included in or attached to this report.
2. If this quarterly report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

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