

# **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 2019



#### Melbourne, Australia, 30 April 2019:

Genetic Technologies Limited (ASX: GTG; NASDAQ: GENE, "Company", "GTG"), a diversified molecular diagnostics company is pleased to provide its Quarterly Activities Report for the period ending 31 March 2019, together with the attached Appendix 4C.

### **Highlights**

- Memorandum of Understanding signed with TGen Arizona work underway on specific cooperation Agreements to develop a commercialization strategy for GTG current and future products
- Intense focus on finalising near term product pipeline through internal R&D efforts.
- Enhanced breast cancer test which increases the applicability of our current BREVAGen*plus®* test to 95% of women remains on schedule for launch in FY19.
- First in class colorectal cancer risk assessment test on schedule for launch in FY19.
- Work continues with the Hainan Provincial Government to establish a market presence in Hainan and also mainland China.
- Kentgrove Capital facility has been accessed by the Company this quarter with net proceeds from activity to be accessed by the Company in the near term.

# Memorandum of Understanding (MoU) signed between GTG and The Translational Genomics Research Institute (TGen) of Phoenix, Arizona USA.

GTG recently announced that it has established an MoU with TGen. TGen is an Arizona-based, non-profit biomedical research institute dedicated to conducting ground-breaking research with life-changing results. TGen works to unravel the genetic components of common and complex diseases, including cancer, neurological disorders, infectious disease, and rare childhood disorders. TGen is affiliated with City of Hope in Duarte, California, a world-renowned independent research and treatment center for cancer, diabetes and other life-threatening diseases

The collaboration will be wide in scope covering:

- Distribution Channels
- Reimbursement Strategy
- Further Research
- Establishment of New Laboratory Facility

Key features include that GTG and TGen will cooperate in the development of a commercialisation strategy and infrastructure development for a suite of polygenic risk tests to be made available in the US market and establish any required fund-raising mechanisms.

In order to achieve these initial goals, GTG and TGen will collaborate on a number of matters including to establish a US-based CLIA laboratory. This will involve, *inter alia*, defining the legal and corporate structure of the collaboration. It will also involve the transfer of GTG's know-how in this area.





Importantly, the TGen collaboration opens up a number of potential distribution channels, as follows:

- Major US Healthcare Systems health care system test availability
- National Cancer Centres testing of cancer patients and family members
- Physician networks physician test ordering
- Large employers/Self-insured employee health and wellness programs
- **Disease consortiums** clinical validity and clinical utility studies
- State Government public health department "endorsement;" public policy; clinical utility studies
- Federal Government regulatory and or policy filings, requirements, or changes

### GTG's Product Development Pipeline

#### Breast cancer test

Development of an enhanced version of the BREVAGen*plus* test is nearing completion. The test will broaden the applicability of BREVAGen*plus* and enable its use by women with an extended family history of disease. By increasing the range of risk factors analysed, the test will provide clinically actionable insight for approximately 95% of women.

#### Colorectal cancer test

Our first-to-market genetic risk assessment test for colorectal cancer is on track to be introduced to the market in FY19. This will be the first of a suite of ground-breaking new products GTG will deliver in the next 12 months.

#### Other genetic risk assessment tests under development

- Cardiovascular Disease
- Type 2 Diabetes
- Prostate Cancer
- Melanoma

These new tests represent the culmination of long-term research initiatives, including our ongoing collaboration with The University of Melbourne.

During the quarter, the Company has progressed discussions with major cancer organisations in the US, Australia and Southeast Asia to develop pilot-scale programs for breast and colorectal cancer genetic risk assessment screening. GTG sees these new tests as the future of predictive medicine through focus on disease risk identification coupled with medically supervised patient-focused preventative actions.

The programs under development demonstrate the acceptance of SNP-based risk assessment testing in both the medical and the scientific communities and highlights the clinical validity of GTG's world-leading tests. Unlike other genetic tests, GTG's screening is clinically validated and based upon years of top level research.

GTG's new genetic testing products present a significant market opportunity for the Company and its developing distribution network partners. There are 8.2 million deaths from cancer per annum, 17.7 million deaths due to cardiovascular disease and 1.6 million deaths due to diabetes (World Health Organisation). Colorectal cancer represents 12.3% of all new cancers diagnosed in Australia in 2018. It is a leading cause of cancer death and disability in Australia and the USA.



# GTG has established operations in China at the Hainan Resort Software Community ("HRSC") Free Trade Zone (Hainan, China)

The move into China includes the formation of Genetic Technologies HK Limited and Hainan Aocheng Genetic Technologies Co. Ltd. in Hong Kong and Hainan, China respectively. Genetic Technologies aims to gain access to the US\$800 billion+ Chinese health market.

As a part of the HRSC, GTG will receive assistance in obtaining China FDA approval for the Company's new and growing portfolio of genetic risk assessment tests, dramatically fast-tracking the 'pathway to sales' process. In addition, as a part of the HRSC, the Company can take advantage of significant tax benefits, subsidies, and facilitated investment. HRSC market entry support includes:

- Marketing assistance providing a link with government sectors, hospitals and other Chinese based health enterprises
- Obtaining test samples to undertake new product development specifically for the Chinese ethnic population
- Chinese corporate registry support
- Office space in the Free Trade Zone precinct and complimentary accommodation for GTG staff
- Provision of a Dedicated HRSC Business Development Director

The Chinese market is now the second biggest single healthcare market outside the United States. Over 4 million new cases of cancer are diagnosed in China every year. Breast cancer is increasing at a rate of over 3.5% each year.

GTG's market entry into China aligns with the government's Healthy China 2030 initiative that seeks to provide cost-effective healthcare to more than 1.5 billion people. Disease prevention is critical to cost control as treatments for early stage disease carry a lower cost and result in better health outcomes.

GTG's genetic tests can be used to predict an individual's likelihood of developing disease. Screening and other healthcare resources can be targeted to those with an elevated risk. For example, screening every woman for breast cancer may be too costly, but it may be cost-effective to preferentially screen those with a mid-to-high risk score.

#### **Capital - Equity Placement Facility**

On 8 August 2018, the Company entered into an Equity Placement Facility with the Kentgrove Capital Growth Fund, an investment fund managed by Kentgrove Capital Pty Ltd, a Melbourne-based investment management firm. Under the Facility, Kentgrove Capital may provide the Company with up to A\$20 million of equity capital in a series of individual placements of up to \$1 million (or a higher amount by mutual agreement) over the next 20 months.

On 25 October 2018, the Company issued 100,000,000 shares under this facility, resulting in cash inflows from financing of \$1.35 million. This facility remains in place and has been utilised at the Board's discretion with net proceeds to be accessed in the near term.



# Quarterly Activities Report for the quarter ended 31 March 2019

## **Financial Snapshot**

Operational cash spend for the quarter was well contained at \$1.4 million, being \$0.2 million less than the previous quarter. The Company's cash receipts remained low and within the expected range during this time of strategic transition, as investment in R&D, development of new product and distribution channels represent the major strategic and budgetary priorities for the Company.

Date: 30 April 2019

Signed on behalf of Genetic Technologies Limited

Dr Paul Kasian

Chairman & Interim CEO

# **Development of Commercialization Strategy** with TGen



# **MOU Signed**

GTG and TGen will cooperate in the development of a commercialisation strategy and infrastructure development for a suite of polygenic risk tests to be made available in the US market.

The collaboration will be wide in scope covering:

- Distribution Channel
- Reimbursement Strategy
- Further Research
- Establishment of New Laboratory Facility

# Translational Genomics Research Institute (TGen): Collaborative Network

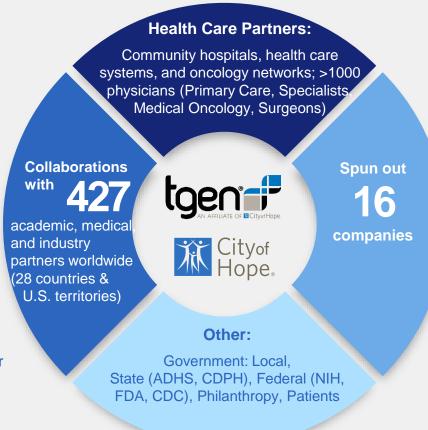


## **Background**

- Est. 2002
- Non-profit (501c3)
- Patient-focused clinical & basic research
- Pioneers in precision genomic medicine
- Expertise includes: Clinicians, laboratory and computer scientists, data analysts, and business development
- Joined City of Hope in Nov. 2016

## **Highlights**

- 1st to perform personalized cancer treatment
- 1st polygenic risk score paper published in 2008 (NEJM)
- 1st to perform whole genome sequencing to inform cancer therapy
- 1st precision medicine trial for children's cancer
- 1st purpose-build genomic supercomputer
- Regularly conduct 1<sup>st</sup> in human clinical trials
- Developer and early adopter of paradigm shifting technologies



#### **Areas of Disease Focus**

- Oncology
- Neurology
- Rare Childhood Disorders
- Diabetes
- Infectious Disease

## **Research Specialties**

- Population Genetics
- Cancer Prevention and Early Detection
- Rare (Childhood) Disease
- Circulating Biomarkers
- Quantitative Medicine
- Infectious Disease
- Tumor Profiling/Drug Selection
- Clinical Trials

# **Basic Computing to High Performance Computing**

**Basic Data Analysis to Quantitative Medicine** 

# **The Distribution Channel**



## The TGen collaboration opens up a number of potential distribution channels:

# I. Major US Healthcare Systems

Distribution opportunity: Health care system test availability

## **II. National Cancer Centers**

Distribution opportunity: Testing of cancer patients an family members

# III. Physician networks

Distribution opportunity: Physician test ordering

# IV. Large employers/Self-insured

Distribution opportunity: Employee health and wellness programs

# **The Distribution Channel**



## V. Disease consortiums

Distribution opportunity: Clinical validity and clinical utility studies

## VI. State Government

Distribution opportunity: Public health department "endorsement;" Public policy; Clinical utility studies

## VII. Federal Government

Distribution opportunity: Regulatory and or policy filings, requirements, or changes

# **The Tgen Clinical Laboratory**



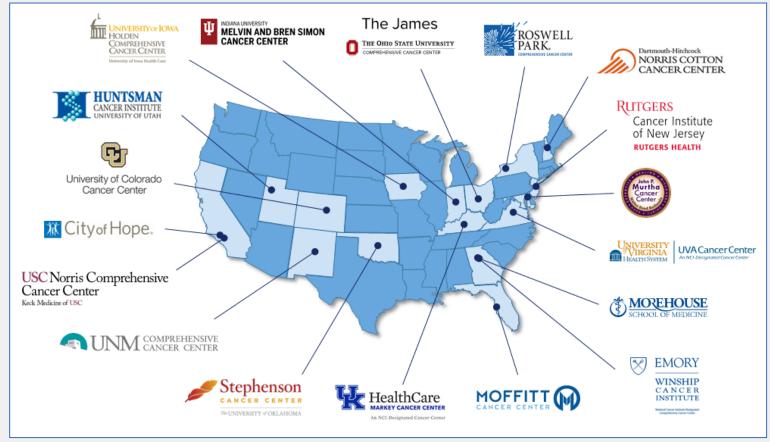
- Founded in 2011, CLIA certified in 2013
- Provided some of the world's first clinical studies for personalized cancer treatment
- Spun out from TGen in 2014, provides commercial access to personalized cancer treatment via genomic profiling of DNA from tumor and normal biospecimens
- In 2018, began serving City of Hope (Duarte, CA) Oncologists and Patients
- In 2018, joined the Oncology Research Information Exchange Network (ORIEN) as one of two molecular sequencing centers delivering informatics-based solutions to accelerate therapy discovery, development and delivery of personalized medicine to 19 of the leading cancer centers in the USA.

# The Tgen Clinical Laboratory



6

## Potential distribution reach across the USA



+Rule 4.7B

## **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

# ABN Quarter ended ("current quarter") 17 009 212 328 31 MARCH 2019

| Consolidated statement of cash flows |  | Current quarter<br>\$A'000 | Year to date<br>(9 Months)<br>\$A'000 |  |
|--------------------------------------|--|----------------------------|---------------------------------------|--|
| 1.                                   | Cash flows from operating activities           |                            |                                       |  |
| 1.1                                  | Receipts from customers                        | 5                          | 162                                   |  |
| 1.2                                  | Payments for                                   |                            |                                       |  |
|                                      | (a) research and development                   | (78)                       | (466)                                 |  |
|                                      | (b) product manufacturing and operating costs  | (4)                        | (22)                                  |  |
|                                      | (c) advertising and marketing                  | (69)                       | (461)                                 |  |
|                                      | (d) leased assets                              | -                          | -                                     |  |
|                                      | (e) staff costs                                | (789)                      | (2,232)                               |  |
|                                      | (f) administration and corporate costs         | (459)                      | (2,092)                               |  |
| 1.3                                  | Dividends received (see note 3)                | -                          | -                                     |  |
| 1.4                                  | Interest received                              | 5                          | 20                                    |  |
| 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 | (1,389)                    | (5,091)                               |  |

1 September 2016

<sup>+</sup> See chapter 19 for defined terms



Appendix 4C Quarterly report for entities subject to Listing Rule 4.7B

| Consolidated statement of cash flows |  | Current quarter<br>\$A'000 | Year to date<br>(9 Months)<br>\$A'000 |
|--------------------------------------|--|----------------------------|---------------------------------------|
| 2.                                   | Cash flows from investing activities           |                            |                                       |
| 2.1                                  | Payments to acquire:                           |                            |                                       |
|                                      | (a) property, plant and equipment              | (2)                        | (5)                                   |
|                                      | (b) businesses (see item 10)                   | -                          | -                                     |
|                                      | (c) investments                                | (250)                      | (250)                                 |
|                                      | (d) intellectual property                      | -                          | -                                     |
|                                      | (e) other non-current assets                   | -                          | -                                     |
| 2.2                                  | Proceeds from disposal of:                     |                            |                                       |
|                                      | (a) property, plant and equipment              | -                          | -                                     |
|                                      | (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 | (252)                      | (255)                                 |

| 3.   | Cash flows from financing activities  |     |       |
|------|---|-----|-------|
| 3.1  | Proceeds from issues of shares  |     | 1,350 |
| 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 | (5) | (8)   |
| 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                              | (5) | 1,342 |

<sup>+</sup> See chapter 19 for defined terms 1 September 2016



Appendix 4C Quarterly report for entities subject to Listing Rule 4.7B

| Consolidated statement of cash flows |   | Current quarter<br>\$A'000 | Year to date<br>(9 Months)<br>\$A'000 |
|--------------------------------------|---|----------------------------|---------------------------------------|
| 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        | 3,235                      | 5,487                                 |
| 4.2                                  | Net cash from / (used in) operating activities (item 1.9 above)       | (1,389)                    | (5,091)                               |
| 4.3                                  | Net cash from / (used in) investing activities (item 2.6 above)       | (252)                      | (255)                                 |
| 4.4                                  | Net cash from / (used in) financing activities (item 3.10 above)      | (5)                        | 1,342                                 |
| 4.5                                  | Effect of movement in exchange rates on cash held                     | (14)                       | 92                                    |
| 4.6                                  | Cash and cash equivalents at end of quarter                           | 1,575                      | 1,575                                 |

| 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<br>\$A'000 | Previous quarter<br>\$A'000 |
|-----|---|----------------------------|-----------------------------|
| 5.1 | Bank balances   | 1,575                      | 3,235                       |
| 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)   | 1,575                      | 3,235                       |

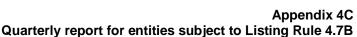
| 6.  | Payments to directors of the entity and their associates                       | Current quarter<br>\$A'000 |
|-----|--|----------------------------|
| 6.1 | Aggregate amount of payments to these parties included in item 1.2             | 123                        |
| 6.2 | Aggregate amount 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

The amount included at Items 6.1 & 6.2 include \$123,239 paid to Directors during the quarter in respect of fees and superannuation.

1 September 2016

<sup>+</sup> See chapter 19 for defined terms



Page 4



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

| 8.  | Financing facilities available Add notes as necessary for an understanding of the position | 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   | 185  | 41                                  |
| 0.4 | Individe helevise description of each facility of  | سماميا مطلع مناميامين ميمم                   | intorest rots and                   |

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, \$35,000 facility with interest at 10.75% p.a.
- 2. Unsecured -National Australia Bank, \$150,000 facility with interest at 12.65% p.a.

| 9.  | Estimated cash outflows for next quarter  | \$A'000 |
|-----|---|---------|
| 9.1 | Research and development                  | 150     |
| 9.2 | Product manufacturing and operating costs | 184     |
| 9.3 | Advertising and marketing                 | 39      |
| 9.4 | Leased assets                             | -       |
| 9.5 | Staff costs                               | 580     |
| 9.6 | Administration and corporate costs        | 589     |
| 9.7 | Other (provide details if material)       | -       |
| 9.8 | Total estimated cash outflows             | 1,542   |

1 September 2016

<sup>+</sup> See chapter 19 for defined terms



Appendix 4C Quarterly report for entities subject to Listing Rule 4.7B

| 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  | -            | -         |

#### **Compliance statement**

- 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.

| ın haraı |  |  |  |
|----------|--|--|--|

| Sign here: |                   | Date: 30 April 2019 |
|------------|-------------------|---------------------|
| _          | Company secretary | ·                   |

Print name: Paul Viney

#### **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.

1 September 2016 Page 5

<sup>+</sup> See chapter 19 for defined terms