



# **GENETIC TECHNOLOGIES LIMITED**

A.B.N. 17 009 212 328

Quarterly Report  
and

Appendix 4C of the ASX Listing Rules

for the quarter ended

**30 June 2020**

**Melbourne, Australia, 29 July 2020:**

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 30 June 2020, together with the attached Appendix 4C.

**Highlights**

- **Successful capital raisings of US\$16.34m before costs**
- **AUD\$20.23m cash balance at 28 July 2020**
- **Genetic Technologies provides update on COVID-19 disease severity test**
- **Consumer Initiated Sales for Existing Pipeline**
- **US Patent Office Grants Key Risk Test Patent**
- **COVID-19 Severity test Provisional Patent Application Filed in Australia**
- **Capability to transition to high throughput Covid-19 testing**
- **Nata and CLIA Lab for USA and Australian Markets**

**Successful capital raisings of US\$16.34m before costs**

The Company has successfully completed capital raisings through bankers HC Wainwright. in the USA. Despite the uncertain economic climate around Covid-19, GTG has successfully raised US\$16.34 (before costs) since the commencement of the June quarter.

- US\$1.8 million raised by the issue on 3 April 2020, of 1,028,574 American Depositary Shares ("ADSs"), each representing six hundred (600) of the Company's ordinary shares, at a purchase price of \$1.75 per ADS - or in Australian dollars \$0.0048 per GTG Share.
- USD 1.44 million raised by the issue on 22 April 2020, of 722,502 American Depositary Shares ("ADSs"), each representing six hundred (600) of the Company's ordinary shares, at a purchase price of \$2.00 per ADS - or in Australian dollars \$0.0053 per GTG Share.
- USD 8 million raised by the issue, on 29 May 2020, of 4,000,000 American Depositary Shares ("ADSs"), each representing six hundred (600) of the Company's ordinary shares, at a purchase price of \$2.00 per ADS - or in Australian dollars \$0.005 per GTG Share.
- USD 5.1 million raised by the issue, on 20 July 2020, of 1,025,000 American Depositary Shares ("ADSs"), each representing six hundred (600) of the Company's ordinary shares, at a purchase price of US\$5.00 per ADS or AU\$0.012 per Share.

Net proceeds raised will be used to support the introduction and distribution of its new products in the United States, for general product research and development and reimbursement studies for polygenic risk tests with TGen in the United States, for implementation of its consumer initiated testing platforms and preparation for its Covid-19 Severity Risk Test.

## Genetic Technologies provides update on COVID-19 disease severity test development

### *Prototype development*

Genetic Technologies is developing a Polygenic Risk Score (PRS) test for COVID-19, which may enable an assessment of risk of an individual developing a serious disease should they contract the COVID-19 virus. The test is intended to predict 'disease severity' using a combination of genetic and clinical information.

- Working prototype developed based on approximately 3,000 patients
- Options for clinical risk model currently being evaluated
- The Company is in discussions with several international biobanks and clinical laboratories to source an independent cross-validation dataset

GTG has established strong relationships with international biobanks and health studies including the UK Biobank that enable GTG to secure additional, current COVID-19 patient data to continuously refine the COVID-19 Risk Test. This data is crucial to the completion of the development and validation of the COVID-19 Risk Test.

### *Implementation*

GTG has commenced ordering its first SNP array panel from USA-based Thermo Fisher Scientific Inc, a world leader in genetic testing and GTG manufacturing partner for GeneType products. The SNP array panel is a key reagent that is required to process the polygenic risk test portion of the COVID-19 Risk Test, which is intended to categorise individuals as being of high, average or low risk of developing life-threatening conditions due to COVID-19.

Furthermore, GTG has confirmed capacity to scale up production for a global-roll out of the COVID-19 Risk Test (reagent and SNP array panel) with major manufacturers, including Thermo Fisher Scientific. The product uses technical components that are already being produced by healthcare manufacturers for other genetic-based tests, which will support GTG's plans to accelerate production to meet anticipated global demand. GTG's Australian facilities will have the capacity of producing up to 250,000 tests per year. The scale-up of manufacturing will require global distribution partnerships if COVID-19 Risk Test is widely adopted.

In anticipation of high demand, GTG expects to make available its data pack to global labs for the COVID-19 Risk Test.

Expenditure on COVID-19 Risk Test includes staff administration costs, patent costs, SNP array design and fabrication, development of algorithms, access to validation data, funds spent to date are estimated to be in the order of \$375K in direct and indirect costs.

### *Regulatory Approval*

Discussions held with Centres for Medicare and Medicaid Services (CMS) and National Association of testing Authorities, Australia ("NATA") for regulatory Approval for Covid-19 Risk Severity Test in the United States and Australia

- A complete technical package will be submitted to the Centres for Medicare and Medicaid Services (CMS) for review and approval.

- CLIA turn-around time for approval expected to be approximately 45 days from submission.
- The submission of the technical file to include scientific literature, algorithm validation, lab wet-work validation and laboratory procedural documentation.
- NATA assessment to be provided upon internal review of Final independent data set for test validation

### ***Intended use***

The test is intended to provide risk stratification information which may help personal and population management in two ways:

- Providing risk stratification to guide quarantine measures on a personal, local, and national scale
- Providing risk stratification to prioritise vaccination if and when a vaccine becomes available

### ***Intellectual property***

Genetic Technologies has filed a provisional patent application for its COVID-19 Risk Test with IP Australia (2020901739 – Methods of assessing risk developing a severe response to Coronavirus infection). The provisional patent covers the specific SNP (Single Nucleotide Polymorphism) algorithm designed by GTG to calculate a PRS and the testing model that combines PRS and the clinical risk factors that together constitute the COVID-19 Risk Test.

### ***Consumer Initiated Sales for Existing Pipeline***

As announced to the market on 1st April 2020, in light of world-wide recommendations on social distancing, which is impacting on our ability to fully engage with physicians, we have brought forward our plans to introduce a Consumer Initiated Testing (CIT) Platform. This sales pipeline deviates from a traditional sales approach that targets clinicians and instead allows patients to request a test directly, with clinician oversight of the testing process through an independent provider network and telemedicine. The Company has now commenced negotiations with its preferred independent provider network who will oversee patient ordering of the CIT pipeline and we expect to announce a binding agreement within the coming month.

### ***US Patent Office Grants Key Risk Test Patent***

In June 2020, the Company was granted US Patent No: US 10,683,549, Methods for assessing risk of developing breast cancer. Genetic Technologies is the first company to successfully commercialise a polygenic risk test for breast cancer in the world.

The granted patent covers our proprietary panels of single nucleotide polymorphisms (SNPs) and the combination of clinical and phenotypic risk models to create the most comprehensive risk assessment tool on the market: GeneType for Breast Cancer.

***Temporary transition to high throughput Covid-19 testing***

Genetic Technologies Limited (Company) has developed a detailed implementation plan to enable a temporary transition of our genetic testing laboratory to a high-throughput Covid-19 testing laboratory, should it be required by Government agencies to assist with demand. Initial work to identify laboratory workflows, instrument modification, laboratory compliance for biologics and contaminated materials handling has commenced. Secure supply chain of test reagents has been confirmed.

***Nata and CLIA Lab for USA and Australian Markets***

GTG has a fully NATA and CLIA accredited laboratory which places it in a unique position to service both the Australian and the USA markets subject to regulatory approvals. Utilising current equipment GTG already owns and is in operation we are in a position to conduct approximately 360,000 tests per annum with the potential to double output as required. Application has been made to Medicare to enable the Company to secure a rebate for tests conducted. To date no requests for such implementation have been received.

***Other information***

During the June quarter total cash payments to directors was \$60,833 comprising of \$24,316 to the acting CEO and \$36,517 to non-executive directors.

Cash receipts for the June quarter were \$2K and cash outflows for the June quarter were \$1,762K.

The additional Capital places the company in the best financial position it has been in for a number of years which will enable it to expand and bring its comprehensive suite of Risk Assessment Tests to market across both Australia and the United States. Laboratory expansion and upgrades incorporating next generation sequencing and high density SNP arrays will also allow for the first time, for 100% of a persons Genomic risk to be assessed including Monogenic, Polygenic, clinical risk factors and family history.

Authorised by Dr George Muchnicki  
Interim CEO

Date: 29 July 2020

## Appendix 4C

### Quarterly cash flow report for entities subject to Listing Rule 4.7B

**Name of entity**

Genetic Technologies Limited

**ABN**

37 080 699 065

**Quarter ended ("current quarter")**

30 June 2020

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (12 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	2	8
1.2 Payments for		
(a) research and development	(409)	(1,029)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(229)	(389)
(d) leased assets	-	-
(e) staff costs	(385)	(1,978)
(f) administration and corporate costs	(977)	(3,972)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	6	22
1.5 Interest and other costs of finance paid	-	(35)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	176	981
1.8 Other (GST refunded)	54	54
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(1,762)</b>	<b>(6,338)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(8)	(16)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	37
	(d) investments	-	43
	(e) intellectual property	-	-
	(f) 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)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>(8)</b>	<b>64</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	17,294	21,794
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(2,198)	(2,811)
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)	-	-
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>15,096</b>	<b>18,983</b>

<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	1,503	2,138
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,762)	(6,338)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(8)	64

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	15,096	18,983
4.5	Effect of movement in exchange rates on cash held	(615)	(633)
4.6	<b>Cash and cash equivalents at end of period</b>	<b>14,214</b>	<b>14,214</b>

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	14,214	1,503
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>14,214</b>	<b>1,503</b>

**6. Payments to related parties of the entity and their associates**

- 6.1 Aggregate amount of payments to related parties and their associates included in item 1
- 6.2 Aggregate amount of payments to related parties and their associates included in item 2

Current quarter \$A'000
61
-

Note: During the quarter the Company made payments to related parties of the entity and their associates as disclosed in Item 6.1 of the Appendix 4C amounting to \$61k. The payments related to salaries, directors fees, and consulting fees on normal commercial terms.



**7. Financing facilities**

*Note: the term "facility" includes all forms of financing arrangements available to the entity.*

*Add notes as necessary for an understanding of the sources of finance available to the entity.*

7.1 Loan facilities

7.2 Credit standby arrangements

7.3 Other (please specify) – Credit Card

7.4 **Total financing facilities**

Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
-	-
-	-
194	5
-	-

7.5 **Unused financing facilities available at quarter end**

189

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

1. Secured – Bank of America, \$25,000 facility with interest at 10.75% p.a.
2. Unsecured – National Australia Bank, \$150,000 facility with interest at 15.5%

**8. Estimated cash available for future operating activities**

**\$A'000**

8.1 Net cash from / (used in) operating activities (Item 1.9)

(1,762)

8.2 Cash and cash equivalents at quarter end (Item 4.6)

14,214

8.3 Unused finance facilities available at quarter end (Item 7.5)

189

8.4 Total available funding (Item 8.2 + Item 8.3)

14,403

8.5 **Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**

8

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

1. Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: N/A

2. Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: N/A

3. Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: N/A

## 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.

Date: 29 July 2020

Authorised by: Justyn Stedwell

Company Secretary

## Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow 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 cash flow 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.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.