

#### Melbourne, Australia, 30 October 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 September 2020, together with the attached Appendix 4C.

#### **Highlights**

- Cash balance of A\$18.1 million as at 30 September 2020 inclusive of the gross proceeds from the capital raise of A\$7.2 million completed in July 2020
- Early initial revenues from the US Platform
- Findings from UK BioBank GTG research submitted for peer review and to medRxiv on GTG's predictive model outlined in the technical paper, 'An integrated clinical and genetic model for predicting risk of severe COVID-19'
- Submission of amended COVID-19 Polygenic Risk Score (PRS) disease severity test (COVID-19 PRS Test) patent to incorporate additional findings on genetic risk stratification
- Development of new polygenic risk scores for Atrial Fibrillation and Coronary Artery Disease. Results submitted for publication and provisional patent application filed
- Development of a polygenic risk test for Type 2 Diabetes with a provisional patent application filed
- Post guarter end launch of Australian Consumer Initiated Testing (CIT) Platform

Genetic Technologies is in a strong position with a solid pipeline of products in development and clear opportunities for the sales and distribution of the launched products being GeneType test for Breast Cancer and for Colorectal Cancer. In addition, the business has a healthy cash position of A\$18.1 million to continue to fund the development of its COVID-19 PRS Test and other products under development.

George Muchnicki stated, "We are pleased with the progress we have made against our key milestones over the quarter. We have established a platform for the sale of our GeneType tests through our Consumer Initiated Testing Platforms and are in the final stages of testing for our COVID-19 PRS Test. The Company has the funding required to progress the development of its suite of products. This is all underpinned by a strong and experienced team able to drive forward with our stated strategy."

#### **Commercialisation Update**

#### COVID-19 Polygenic Risk Score Test

Genetic Technologies has continued to progress its COVID-19 PRS Test and is currently in final stages of testing following the successful modelling of 1,500 UK biobank participants as outlined in the published paper by GTG, An integrated clinical and genetic model for predicting risk of severe COVID-19.

Available here: https://www.medrxiv.org/content/10.1101/2020.09.30.20204453v1.full.pdf



The findings of the COVID-19 PRS Test model incorporating the single-nucleotide polymorphism (SNP) score and clinical risk factors was applied to the UK Biobank data consisting of data on over 1,500 individuals over the age of 50 with clinically confirmed COVID-19. The findings from the model included a 111% better discrimination of the disease severity than age and gender alone. These results further highlight that continuing to rely on age and gender to determine risk of severe COVID-19 may unnecessarily classify healthy older people as being at high risk and will fail to accurately quantify the increased risk for younger people with comorbidities.

GTG's risk prediction test for severe COVID-19 in people aged 50 years or older has the potential to manage the risk for essential workers, in healthcare settings and in workplaces that seek to reopen safely. The test will also enable individuals to make informed choices based on their personal risk. However, key to understanding the performance of our risk prediction test will be validation in independent data sets, work that GTG intends to undertake in the near term.

The Company confirms receipt of the Thermo Fisher arrays and are undertaking GTG laboratory based technical validation as part of the final stage testing and are in the process of working with Thermo Fisher on design modifications of the kit. GTG are concurrently validating the use of two alternative genotyping platforms to mitigate, in advance, any technical risks with the intent to offer the test commercially at the earliest opportunity.

Upon completion of the final stage testing the Company is in late stage conversations to partner with a US based laboratory to provide the scale-up of manufacturing required to address global distribution of the COVID-19 PRS Test, subject to final approvals and confirmed validation of the test.

Substantial effort and resources continue to be applied to the development and launch of the COVID-19 PRS Test.

#### GeneType for Breast Cancer and Colorectal Cancer

GTG launched the US based CIT Platform in April 2020. The Company appointed its preferred independent provider in the US, Intelelabs, who will oversee patient ordering of the CIT pipeline.

The Company is currently capable of processing approximately 360k tests per annum leveraging existing equipment GTG owns. The Company also has the potential to double output if required. Discussions have commenced with Medicare to enable the Company to secure a rebate for tests conducted.

Post quarter end, Genetic Technologies launched the Australian-based CIT platform. This platform, along with the US counterpart, will enable the sale of tests to be initiated directly by consumers in Australia and the US for both the GeneType for Breast Cancer and Colorectal Cancer tests.

As previously outlined, 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.

Additionally, the Company intends to provide access to the testing kits for the COVID-19 PRS test via this platform. To visit our CIT platform please follow the link below.

www.genetype.com.au



The CIT platforms are the first stage of the Company's sales and marketing strategy. Additional avenues for promotion of the products will be via direct marketing to physicians. Within Australia, the first stage of this approach will be via two bespoke medical sales firms, engaged to provide access to Australia's largest audience of General Practitioners (GPs) through the Royal Australian College of General Practitioners (RACGP) and The Australian College of Rural and Remote Medicine (ACRRM). As part of this engagement, GTGs Genetic Breast Cancer Programme are expected to be accredited and be made available as part of the Australian GPs Continued Professional Development Programme to potentially provide education for up to 35,000 doctors on the clinical benefits and utility of our tests.

#### GeneType Polygenic Risk Test Pipeline

The Company has successfully developed new polygenic risk tests for Atrial Fibrillation, Coronary Artery Disease and Type 2 Diabetes. The results have been submitted for publication in peer-reviewed medical journals and a provisional patent application filed covering the underlying technology.

Dr Richard Allman, Genetic Technologies Chief Scientific Officer, commented "Clinical risk algorithms for cardiovascular disease perform quite well and it is technically difficult to improve them by adding genetic markers. We are extremely pleased that we have been able accomplish that feat in a relatively short period."

Genetic Technologies are currently working on the transition of the Type-2 Diabetes test to move towards commercialisation which will encompass further laboratory validation and the creation of the technical packs. Following this GTG will work with the National Association of Testing Authorities (NATA) and Clinical Laboratory Improvement Amendments (CLIA) to attain the required accreditation. The process is anticipated to be complete in the first half of calendar year 2021 and once complete the Atrial Fibrillation and Coronary Artery Disease tests are anticipated to follow.

The team are also continuing to progress the development of the Melanoma and Prostate test, however, in order expedite the COVID-19 PRS Test it was necessary to reassign resources originally allocated to these tests. GTG anticipate that, subject to resource capacity, the development of these tests will be complete in the first half of 2021.

#### **Intellectual Property and Regulatory Approvals**

GTG has submitted an update to the previously filed provisional patent application for its COVID-19 PRS Test with IP Australia (2020901739 – Methods of assessing risk developing a severe response to Coronavirus infection) as submitted on 27 May 2020. The amendments were filed on 30 September 2020 and incorporated GTG's latest findings as outlined in the technical paper.

The provisional patent application covers the specific SNP algorithm designed by GTG to calculate the PRS and the testing model that combines the PRS test and the clinical risk factors that together constitute the COVID-19 PRS Test.

The Company will now expand this online sales capability by making the COVID-19 PRS Test available to US customers, targeted as a Q4 2020 release.



#### **Corporate and Financial Overview**

During the September quarter, net cash payments to directors was A\$103,934 comprising of A\$24,691 to the acting CEO, A\$40,743 to non-executive directors and consulting fees paid to a non-executive director of A\$38.500.

Cash receipts from operating activities for the September quarter were A\$7k and cash outflows used in operating activities for the September quarter were A\$1.9 million. Expenses incurred during the quarter included research and development costs of A\$438k associated with progressing the COVID-19 PRS Test. Additionally, the Company incurred A\$134k associated mainly with the purchase of inventory and the consumer initiated testing platform in the United States of America.

As previously disclosed, total gross proceeds from the settlement of the capital raise completed within the September quarter was A\$7.2 million/ USD\$5.1 million. The Company is utilising the net proceeds 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 CIT platforms and preparation for its COVID-19 PRS Test as well as for working capital and potential acquisitions

#### **Investor Webinar**

The Company will provide an update on further advancements to its diagnostic tests and hold an investor webinar to discuss the quarterly update, on Friday 30 October 2020 at 11:30am AEDT.

To participate on the quarterly investor webinar, please register at: https://us02web.zoom.us/webinar/register/WN\_mkXCxcAlSJizX3DP0gYuug

Authorised by Dr George Muchnicki Interim CEO Directors

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Date: 30 October 2020

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About Genetic Technologies Limited Genetic Technologies Limited (ASX: GTG; Nasdaq: GENE) is a diversified molecular diagnostics company. GTG offers cancer predictive testing and assessment tools to help physicians proactively manage patient health. The Company's lead products GeneType for Breast Cancer for non-hereditary breast cancer and GeneType for Colorectal Cancer are clinically validated risk assessment tests and are first in class. Genetic Technologies is developing a pipeline of risk assessment products.

For more information, please visit www.gtglabs.com

### **Appendix 4C**

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

#### Name of entity

Genetic Technologies Limited

### ABN

#### Quarter ended ("current quarter")

37 080 699 065

30 September 2020

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000	
1.	Cash flows from operating activities			
1.1	Receipts from customers	7	7	
1.2	Payments for			
	(a) research and development	(438)	(438)	
	(b) product manufacturing and operating costs	(134)	(134)	
	(c) advertising and marketing	(54)	(54)	
	(d) leased assets	(98)	(98)	
	(e) staff costs	(379)	(379)	
	(f) administration and corporate costs	(978)	(978)	
1.3	Dividends received (see note 3)	-	-	
1.4	Interest received	19	19	
1.5	Interest and other costs of finance paid	-	-	
1.6	Income taxes paid	-	-	
1.7	Government grants and tax incentives	180	180	
1.8	Other : GST to ATO	-	-	
1.9	Net cash from / (used in) operating activities	(1,875)	(1,875)	

2.	Cash flows from investing activities		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(450)	(450)

ASX Listing Rules Appendix 4C (17/07/20)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(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)	-	-
2.6	Net cash from / (used in) investing activities	(450)	(450)

3.	Cash flows from financing activities		
3.1	Proceeds from (payments for) issues of equity securities (excluding convertible debt securities)	7,222	7,222
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	148	148
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(938)	(938)
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	6,432	6,432

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	14,214	14,214
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,875)	(1,875)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(450)	(450)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	6,432	6,432
4.5	Effect of movement in exchange rates on cash held	(226)	(226)
4.6	Cash and cash equivalents at end of period	18,095	18,095

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	18,095	14,214
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)	18,095	14,214

6.	Payments to related parties of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	104
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

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 \$104k. 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
-	-
-	-
192	2
-	-

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

190

- 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.
  - 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)	(1,875)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	18,095
8.3	Unused finance facilities available at quarter end (Item 7.5)	190
8.4	Total available funding (Item 8.2 + Item 8.3)	18,285
8.5	Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	9.8

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

- 8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:
  - 8.6.1 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	

8.6.2 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			

8.6.3 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

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

#### **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.

Date: 30 October 2020

Authorised by: Justyn Stedwell

Company Secretary

#### **Notes**

- 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.
- 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.