

**Melbourne, Australia, 28 January 2021:**

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 December 2020, together with the attached Appendix 4C.

**Highlights**

- Cash balance of A\$16.43 million as at 31 December 2020
  - Post quarter end the Company completed a US\$6.56 million (A\$7.69 million) US capital raise
- Net cash used for operations of A\$1.48 million a decrease on prior quarter (Q1 FY21: A\$1.88 million)
- Partnered with Taliaz for the sale and distribution rights of PREDICTIX in Australia, New Zealand and the US providing the first foray into pharmacogenetics for GTG
- Expansion of product base into existing reimbursable segments with BRCA and Lynch Syndrome to allow for a platform or whole of disease approach to genetic risk testing
- COVID-19 PRS test is undergoing technical validation with an expanded data set and is expected to be commercially available by the end of Q1 CY21, subject to regulatory approvals
- Post quarter end appointment of Simon Morriss as Chief Executive Officer effective 1 February 2021

Genetic Technologies has further expanded its products in development with the inclusion of Germline testing for BRCA and Lynch Syndrome. This expansion will enable GTG to provide reimbursable products in conjunction with GTG’s developed PRS tests providing enhanced genetic risk cover.

The Company remains in a strong position with A\$16.43 million in cash to advance the development of its pipeline of products and is progressing opportunities for the sales and distribution of the launched products being GeneType test for Breast Cancer and for Colorectal Cancer.

George Muchnicki stated, “This past quarter has seen our product base expand with the sales and distribution agreement with Taliaz and the opportunity to enter the reimbursable market with the introduction of the development of BRCA and Lynch Syndrome Germline testing capabilities. These products will enable the Company to provide wholistic risk assessment tests for doctors and their patients and are anticipated to be available in the second half of the calendar year.

“The technology and accuracy of the algorithm behind the COVID-19 PRS test has advanced markedly with the inclusion of an additional ~4,000 patient data set. By undertaking further technical validation with this dataset we have enhanced the accuracy and quality of data associated with our COVID-19 PRS Test algorithm and expect to have the product commercially ready by the end of Q1 CY21. In light of resources constraints, we are pleased with the team’s ability to make significant progress on the COVID-19 test at the same time as we have introduced new products into the portfolio.

“The Company continues to progress against its strategy to be a leader in predictive medicine supported by an exceptional team of industry professionals.”

## Product Overview and Regulatory Progress

### *GeneType Breast Cancer and Colorectal Cancer Screening*

The Company's two products in market are available via the Australian and US CIT platform. Intelabs continue to oversee patient ordering of the CIT site in the US with Phenix Health providing oversight on the Australian based site.

The Company is currently capable of processing approximately 360k GeneType tests per annum by leveraging existing owned equipment. 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 PRS tests conducted, this remains a longer-term objective and is expected to support distribution through the B2B channel.

### *Germline Testing Platform*

GTG have established the Germline Testing division following the strategic decision to offer hereditary testing for inherited cancer. The initial product focus for the division will be on BRCA testing and Lynch Syndrome test to align with GTG's GeneType products for Breast Cancer and Colorectal Cancer respectively.

This approach provides several strategic benefits, being the ability to identify cancer risk across the spectrum of cancer causation, from hereditary cancers caused by monogenic mutations to sporadic cancers with a polygenic, multifactorial cause. BRCA and Lynch Syndrome tests also have existing reimbursement codes which provide a clear pathway to monetisation.

Further announcements regarding the progression within the hereditary cancer testing will be provided as the Company progresses with the development and validation process.

### *PREDICTIX by Taliaz*

As announced in December 2020, the Company has entered into a three-year partnership agreement with Taliaz for the distribution of their core product, PREDICTIX. The product uses a combination of genetic, metabolic, clinical and demographic background data in conjunction with artificial intelligence and machine learning to enable more accurate prescription of anti-depressants.

It is anticipated that the Taliaz product will be available for market release in the second half of calendar year 2021 via the CIT platforms in the US and Australia, subject to regulatory approvals from Clinical Laboratory Improvement Amendments (CLIA) and National Association of Testing Authorities (NATA). Over time there is considerable opportunity to distribute the product into the mental health channel and integrate PREDICTIX into GTG's Multitest platform.

Inclusion of PREDICTIX in the product portfolio is consistent with GTG's strategy of supplementing its proprietary portfolio with complementary third-party technology, where there is strong commercial rationale to do so. GTG will continue to allocate its inhouse research and development efforts towards market opportunities where it is best positioned to create value.

### *COVID-19 Polygenic Risk Score Test*

Genetic Technologies has continued to advance its COVID-19 PRS Test, having analysed data on more than 5,500 infected patients following the UK biobank's release of ~4,000 confirmed COVID-19 positive patients in November 2020.

The expanded data analysis has enhanced validation of the predictive capabilities of GTG's COVID-19 PRS test, which now offers over 100%<sup>1</sup> predictive accuracy than disease risk severity based on age and gender alone, and the test has been confirmed to be well calibrated<sup>2</sup>.

Additional datasets are expected to become available over the coming months and will be included in the platform to further enhance the predictive capabilities of the algorithm. These enhancements are not expected to impede progress towards regulatory submission to the Centers for Medicare and Medicaid Services/Clinical Laboratory Improvement Amendments (CMS/CLIA), anticipated by the end of Q1 CY21.

The COVID-19 test was originally conceived as a personal and population-based risk management tool. Potential applications have broadened, and it is now evident the test is likely to assist Governments and healthcare bodies in the prioritisation of vaccine delivery. The Company also anticipates that knowledge gained may provide valuable insight for the development of a broadly applicable infectious-disease susceptibility model in the future.

#### *GeneType Polygenic Risk Test Pipeline*

In addition to the two products in market, the Company currently has four products in final stage development with submission to CLIA and NATA expected within the coming months, three products in development and two products under early-stage consideration.

As outlined in the last quarter GTG developed new PRS tests for Atrial Fibrillation, Coronary Artery Disease and Type 2 Diabetes which are currently under development and will continue to be progressed over the coming periods as we move to complete further laboratory validation and the creation of the technical packs. Following this GTG will work with NATA and CLIA to attain the required clearance.

GTG have prioritised those tests which will provide the strongest commercialisation opportunities given current laboratory bandwidth for product development. With the prioritisation of the BRCA and Lynch Syndrome germline tests, management considered it prudent to defer the completion of the Type 2 Diabetes, Atrial Fibrillation and Coronary Artery Disease tests to later in calendar year 2021. Additionally, the development of the Melanoma and Prostate tests has been delayed to the first half of calendar year 2021 to optimise the allocation of resources to complete the development of the COVID-19 PRS test.

GTG continues to focus on publications of relevant content for submission to peer-reviewed journals. Over the quarter the team have drafted articles for publication in the coming periods, however publications and releases are subject to product development and submissions to CLIA and NATA and, where appropriate, securing intellectual property rights.

#### **Commercialisation Update**

The Company has previously outlined its key avenues for commercialisation of launched products which currently include:

- The consumer-initiated testing and online sales and marketing platform (CIT) available in Australia and the US. The CIT platforms are the first stage of the Company's sales and marketing strategy.

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<sup>1</sup> Predictive accuracy of the test as assessed by analysis of the Area Under the Receiver Operating Characteristic Curve

<sup>2</sup> Calibration assessed using Pearson-Windmeijer goodness-of-fit test

Sales via medical professionals for business to business (B2B) purposes. This involves a direct sales approach, in addition to the Company's education program to enhance general knowledge, understanding and acceptance of genetic testing to assist with reducing patient mortality through early intervention.

The Company is currently working on:

- Reimbursement avenues via the Germline testing platform for BRCA and Lynch Syndrome
- Direct to consumer testing with no medical supervision for products under consideration including ancestry and gut microbiome testing

## Intellectual Property

GTG's patent portfolio remains robust. There were no updates on the outcome of the previously filed provisional patent application for the COVID-19 PRS test during the quarter. GTG will continue to revise or add to their patent portfolio where required.

## Corporate and Financial Overview

During the December quarter, net cash payments to directors was A\$111k comprising of A\$53k to the acting CEO, A\$34k to non-executive directors and consulting fees paid to a non-executive director of A\$24k.

Cash outflows used in operating activities were \$1,481k. Cash receipts from customers for the December quarter were A\$8k and from interest received and government grants/tax incentives were A\$12k and A\$198k respectively. Expenses incurred during the quarter included research and development costs of A\$358k associated with progressing the COVID-19 PRS Test and the introduction of the germline testing division. Additionally, the Company incurred A\$63k associated with product manufacturing and sales and marketing with expenditure expected to increase as the company enhances its sales and marketing focus in the upcoming quarters.

Post quarter end, the Company completed a US\$6.56 million capital raise<sup>3</sup> on the 25<sup>th</sup> January 2021 via a placement to several US based institutional investors. The Company intends to use the net proceeds from this offering to:

- Support the introduction and distribution of its new products in the United States and Europe;
- Reimbursement studies for the polygenic risk tests;
- Implementation of its consumer-initiated testing platforms;
- Preparation for its COVID-19 PRS Test;
- Introduction of germline testing division;
- General product research and development; and
- For general working capital and potential acquisitions.

Additionally, the Company announced the appointment of Simon Morriss to the position of Chief Executive Officer, commencing 1 February 2021. Simon brings over 20 years' experience within the Pharmaceutical, Healthcare and FMCG industries having held senior executive positions at Sanofi and Blackmores. He has been critical in leading commercialisation across these industries and understands the unique pressures and opportunities.

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<sup>3</sup> Before deducting the placement agent's fees and other offering expenses payable by the Company.

Acting CEO, Dr George Muchnicki, will be stepping into the role of Chief Medical Officer and Executive Director and will continue to leverage his exceptional background and experience to continue to advance product development and establish the medical framework for GTGs platform offering.

### **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 Thursday 28 January 2021 at 11:30am AEDT.

To participate on the quarterly investor webinar, please register at:  
[https://us02web.zoom.us/webinar/register/WN\\_gy5DGFNMSKiAYfYeV0Ygpg](https://us02web.zoom.us/webinar/register/WN_gy5DGFNMSKiAYfYeV0Ygpg)

Authorised by the Board of Genetic Technologies

Date: 28 January 2021

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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](http://www.gtglabs.com)

## Glossary of terms and acronyms

**Clinical Laboratory Improvement Amendments (CLIA)** - Regulates laboratory testing and require clinical laboratories to be certified by the Center for Medicare and Medicaid Services (CMS) before they can accept human samples for diagnostic testing

**Consumer Initiated Tests (CIT)** - laboratory testing that is initiated by the consumer without a physician order but reviewed and communicated back to the consumer via a physician.

**Direct to Consumer (DTC)** – laboratory testing that is initiated by the consumer without a physician order. The results are reported back directly to the consumer.

**Genome Wide Association Studies (GWAS)** - an approach used in genetics research to associate specific genetic variations with particular diseases. The method involves scanning the genomes from many different people and looking for genetic markers that can be used to predict the presence of a disease. Once such genetic markers are identified, they can be used to understand how genes contribute to the disease and develop better prevention and treatment strategies.

**Germline Testing** – Germline testing is done on cells that do not have cancer. It is done to see if a person has a gene mutation that is known to increase the risk of developing cancers and other health problems. This test uses cells (such as blood or skin cells) that do not have any cancer cells. Germline mutations can sometimes be passed down from parents.

**Laboratory Developed Tests (LDT)** – A type of in vitro diagnostic test that is designed, manufactured and used within a single laboratory.

**Polygenic Risk Score (PRS)** - A polygenic risk score tells you how a person's risk compares to others with a different genetic constitution. However, polygenic scores do not provide a baseline or timeframe for the progression of a disease. For example, consider two people with high polygenic risk scores for having coronary heart disease.

**Serious Disease Risk (SDR)** - Risk associated with acquiring COVID-19 and requiring hospitalisation with its associated morbidities and mortalities.

**National Association of Testing Authorities (NATA)** - the authority responsible for the accreditation of laboratories, inspection bodies, calibration services, producers of certified reference materials and proficiency testing scheme providers throughout Australia. It is also Australia's compliance monitoring authority for the OECD Principles of GLP. NATA provides independent assurance of technical competence through a proven network of best practice industry experts for customers who require confidence in the delivery of their products and services.

**Next Generation Sequencing (NGS)** – Next-generation sequencing (NGS), also known as high-throughput sequencing, is the catch-all term used to describe a number of different modern sequencing technologies. These technologies allow for sequencing of DNA and RNA much more quickly and cheaply than the previously used Sanger sequencing, and as such revolutionised the study of genomics and molecular biology.

**Single nucleotide polymorphisms (SNPs)** - the most common type of genetic variation among people. Each SNP represents a difference in a single DNA building block, called a nucleotide

## 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")**

31 December 2020

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (6 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	8	15
1.2 Payments for		
(a) research and development	(358)	(796)
(b) product manufacturing and operating costs	(63)	(197)
(c) advertising and marketing	(76)	(130)
(d) leased assets	(96)	(194)
(e) staff costs	(235)	(614)
(f) administration and corporate costs	(871)	(1,849)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	12	31
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	198	378
1.8 Other (provide details if material)		
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(1,481)</b>	<b>(3,356)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(106)	(556)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-



Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
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)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>(106)</b>	<b>(556)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	7,222
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	148
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	(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)	-	-
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>-</b>	<b>6,432</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	18,095	14,214
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,481)	(3,356)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(106)	(556)



Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	6,432
4.5	Effect of movement in exchange rates on cash held	(73)	(299)
4.6	<b>Cash and cash equivalents at end of period</b>	<b>16,435</b>	<b>16,435</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	6,405	18,095
5.2	Call deposits	10,030	-
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>16,435</b>	<b>18,095</b>

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	111
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<p>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 \$111k. The payments related to the net pay of salaries, directors fees and consulting fees (inclusive of GST) on normal commercial terms.</p>		

<b>7.</b>	<b>Financing facilities</b> <i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i> <i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	189	10
7.4	<b>Total financing facilities</b>	<b>189</b>	<b>10</b>
7.5	<b>Unused financing facilities available at quarter end</b>		179
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 9.25% 2. Unsecured – National Australia Bank, \$150,000 facility with interest at 15.5%		

<b>8.</b>	<b>Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1	Net cash from / (used in) operating activities (item 1.9)	(1,481)
8.2	Cash and cash equivalents at quarter end (item 4.6)	16,435
8.3	Unused finance facilities available at quarter end (item 7.5)	179
8.4	Total available funding (item 8.2 + item 8.3)	16,614
8.5	<b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	11.2
	<i>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.</i>	
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	
	<i>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.</i>	

## 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: 28 January 2021

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.