Genetic Technologies

Quarterly Activities Report
for the quarter ended **31 March 2021**

Melbourne, Australia, 29 April 2021:

Genetic Technologies Limited (ASX: GTG; NASDAQ: GENE, "Company", "GTG"), a diversified Genomics and AI driven preventative health care business company is pleased to provide its Quarterly Activities Report for the period ending 31 March 2021, together with the attached Appendix 4C.

Highlights

- Strong cash balance of A$22.98 million as at 31 March 2021 provides runway to fund current planned commercialisation opportunities and product development
- Net cash used for operations of A$1.08 million a decrease on prior quarter (Q2 FY21: A$1.48 million)
- The Company received A$0.7 million in R&D Tax Refund payments
- Signed landmark multiyear US licence agreement with Infinity Biologix for the COVID-19 Serious Disease Risk Test
- Post quarter end, confirmed the regulatory approval for the commercial release of the COVID-19 Risk Test in the United States (ref: ASX Announcement 26 April 2021)
- Engaging with government to discuss the importance of preventative health and precision medicine with a recent engagement with Senator David Van facilitated by Research Australia
- Appointment of Simon Morriss to the role of Chief Executive Officer and post quarter end appointment of Mike Tonroe to the role of Chief Financial Officer

Simon Morriss, CEO of Genetic Technologies, stated "This quarter was a key inflection point in the Company's transition from its research focused heritage to active commercialisation of its product base. We are proactively focused on pursuing further commercialisation opportunities for our products in development to follow on from the signing of our first multi-year sales and distribution agreement with US based Infinity Biologix ('IBX') for our COVID-19 Serious Disease Risk Test ('COVID-19 Risk Test').

"The landmark co-exclusive licence agreement not only validated GTG's technology and capabilities, but also provides a substantial distribution opportunity for our COVID-19 Risk Test in conjunction with the over 100,000 SARS-CoV-2 tests IBX processes per day.

"This marks the first agreement that leverages the initiatives and products the team have developed. We anticipate that as we progress our product development pipeline that further distribution opportunities will be established and will embed GTG as an innovative company focused on diversified genomics and AI driven preventative healthcare."

Commercialisation Update

Licence Agreement for COVID-19 Serious Disease Risk Test

The three-year co-exclusive licence agreement between IBX and GTG for the production, distribution, sales and marketing of GTG's COVID-19 Risk Test in the US, announced on 3 March 2021, represents a key advancement in the company's commercialisation strategy during the quarter.

IBX are a leading central laboratory in the US, supporting academia, government, and industry. Through three well established labs and a network of testing partners, IBX provide sample collection and processing, storage, and analytical services, integrated with scientific and technical support in both the research and clinical arenas.

IBX is required to make minimum payments to GTG totaling US$2.9 million over the three-year term to maintain exclusivity. Revenues can exceed these levels through the underlying royalty structure, whereby GTG will be paid US$10 on a per test basis.

IBX have the capacity to process over 100,000 COVID-19 Risk Tests per day and is well positioned with an existing network of SARS-CoV-2 testing partners and associated medical practitioners across the US.

The Company confirms the submission of the COVID-19 Risk Test regulatory pack to the regulators[1]. In conjunction with prior correspondence with the regulators this submission enables the commercial release within the United States Final steps in the technical interface are being built with additional capabilities for the telehealth platform to enable sales of GTG's COVID-19 Risk Test and further products[2] within markets outside of the United States. The Company will provide further updates on regional releases as and when they are confirmed.

The commercial release is expected to occur no later than the end of May once the technical interface for the United States telehealth platform is completed by IBXs telehealth partners.

Commercialisation Strategy for Broader Product Portfolio

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. Additionally, GTG are engaging in sales via medical professionals for business to business (B2B) purposes and direct to consumer (DTC) products under consideration including non-medical based genetic and gut microbiome testing, subject to regulatory approval of target markets.

With GTG now having distribution coverage of the Australian and US geographies. Europe and the UK are the next regions the company intends to enter, and the Company is assessing the CE certification requirements for its products and will update the market on its progress within this geography as further clarity on timing is obtained. An Asian market entry for relevant products will also be assessed in due course.

Product Overview and Regulatory Progress

GeneType Breast Cancer and Colorectal Cancer Screening and Germline Testing Platform

GTG continues to progress the development of its Germline Testing division for hereditary testing. The initial BRCA and Lynch Syndrome tests, that align with GTG's GeneType products in market for Breast Cancer and Colorectal Cancer respectively, are anticipated to launch by the end of CY21. These tests are being structured to include all known hereditary and non-

1 Regulators include the Centres for Medicare and Medicaid Services / Clinical Laboratory Improvement Amendments (CMS/CLIA) and New York State Department of Health (NYSDOH)/Clinical Laboratory Evaluation Program (CLEP). For COVID-19 testing, we are following a policy March 2020 FDA policy allowing laboratories to initiate patient testing once the assay has been:
a) Validated and approved by the laboratory director/ responsible Certificate of Qualification Holder; and
b) Submitted to CLEP via hard copy and digital.

2 COVID-19 Risk Test availability within expanded markets outside of the United States subject to regulatory approvals for each region.

hereditary risk factors across the Germline tests and GTG's PRS testing. BRCA and Lynch Syndrome tests also have existing reimbursement codes, which provides a clear pathway to monetisation and an opportunity to bundle with their associated PRS tests.

The Company continues to engage in discussions 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.

COVID-19 Risk Test

In November 2020, Genetic Technologies incorporated the expanded COVID-19 Risk Test data set which included an additional ~4,000 infected patients following the UK biobank's release of confirmed COVID-19 positive patients. Following this and outlined above the Company has signed a three-year co-exclusive licence agreement with IBX for the production, distribution, sales and marketing of GTG's COVID-19 Risk Test in the US.

GeneType Multitest

GTG's PRS products under development will ultimately be offered as part of the GeneType Multitest platform, which will provide risk assessment for greater than 70% of all morbidities including Breast Cancer, Colorectal Cancer, Cardiovascular Disease, Type 2 Diabetes, Melanoma and Prostate Cancer. Products for each morbidity will be offered both as standalone tests and as part of the consolidated Multitest offering. Updates on product progression and the Multitest offering will be provided as progressed over CY21.

GTG have confirmed TGA clearance of the PREDICTIX product by Taliaz and will be highlighting the product at the upcoming General Practice Conference and Exhibition (GPCE) in Sydney in mid-May.

Research and Publications

GTG continues to focus on publications of relevant content for submission to peer-reviewed journals. The Company confirms the below articles, authored by employees of Genetic Technologies, were made available over the quarter and are still subject to peer-review process, on the MedRxiv preprint server site under the titles of:

- 'Development and validation of a clinical and genetic model for predicting risk of severe COVID-19' authored by Dite, Murphy and Allman; and

- 'The health effects in the US of quarantine policies based on predictive individual risk of severe COVID-19 outcomes' authored by Lovick, Dite and Allman

Before formal publication in a scholarly journal, scientific and medical articles are traditionally certified by "peer review." In this process, the journal's editors take advice from various experts—called "referees"—who have assessed the paper and may identify weaknesses in its assumptions, methods, and conclusions. Typically, a journal will only publish an article once the editors are satisfied that the authors have addressed referees' concerns and that the data presented support the conclusions drawn in the paper. Because this process can be lengthy, authors use the medRxiv service to make their manuscripts available as "preprints" before certification by peer review, allowing other scientists to see, discuss, and comment on the findings immediately. Readers should therefore be aware that articles on medRxiv have not been finalized by authors, might contain errors, and report information that has not yet been accepted or endorsed in any way by the scientific or medical community. Work that appears on medRxiv preprints has yet to be evaluated by the medical community and the information presented may be erroneous.

The Dite, Murphy and Allman article outlines the outcomes from the analysis of an updated dataset of 2,205 cases and 5,416 control patients. The increased sample numbers have enabled separation into test and validation datasets, a key requirement for commercialisation.

The COVID-19 pandemic continues to be at the forefront of public health discussions with varying success on infection control measures and social distancing protocols. The Company has therefore conducted modelling studies to evaluate the application of the COVID-19 Risk Test in workforce and population management, described in the Lovick, Dite and Allman article.

Social distancing demonstrably reduces pandemic harm but comes with potential significant economic cost. This study was designed to understand whether the economic harms could be mitigated by a targeted approach to population management based on an assessment of likely individual COVID-19 severity.

Both papers have been simultaneously submitted for publication in peer-reviewed scientific journals, however, given the COVID-19 pandemic, the Company has made the data publicly available on the pre-print site at this early stage.

Corporate and Financial Overview

During the March quarter, net cash payments to directors was A$92k comprising salary of A$34k to the Chief Medical Officer (formerly the acting Chief Executive Officer), A$41k to non-executive directors, and consulting fees paid to a non-executive director of A$17k.

Cash outflows used in operating activities were $1,084k. Cash receipts from customers for the December quarter were A$6k and interest received, and government grants/tax incentives were A$5k and A$763k respectively. Expenses incurred during the quarter included research and development costs of A$581k associated with progressing the COVID-19 Risk Test and the introduction of the germline testing division. Additionally, the Company incurred A$67k 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.

Simon Morriss commenced as Chief Executive Officer on 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.

Post quarter end, the Company announced the appointment of Michael Tonroe to the role of Chief Financial Officer commencing in June 2021. Michael has over 25 years' experience in overseeing the finance function at both management and board-level positions for private and listed companies in Australia, UK, US and Canada. He also has extensive experience in the biotech space across both the financial and company secretary roles having most recently managed both functions for dual-listed Opthea Limited.

Authorised by the Board of Genetic Technologies Date: 29 April 2021

Investor Relations (AUS)
Stephanie Ottens
Market Eye
M: +61 434 405 400
E: stephanie.ottens@marketeye.com.au

Investor Relations and Media (US)
Dave Gentry
1 800 RED CHIP (733 2447)
Cell: 407 491 4498
E: dave@redchip.com

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

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	**Quarter ended ("current quarter")**
17 009 212 328	31 March 2021

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (9 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	6	21
1.2	Payments for		
	(a) research and development	(581)	(1,377)
	(b) product manufacturing and operating costs	(67)	(264)
	(c) advertising and marketing	(102)	(232)
	(d) leased assets	(98)	(292)
	(e) staff costs	(275)	(889)
	(f) administration and corporate costs	(735)	(2,584)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	5	36
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	763	1,141
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(1,084)**	**(4,440)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(26)	(582)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 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)	-	-
2.6	**Net cash from / (used in) investing activities**	**(26)**	**(582)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	8,488	15,710
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	40	188
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(990)	(1,928)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	**Net cash from / (used in) financing activities**	**7,538**	**13,970**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	16,435	14,214
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,084)	(4,440)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(26)	(582)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	7,538	13,970
4.5	Effect of movement in exchange rates on cash held	121	(178)
4.6	**Cash and cash equivalents at end of period**	**22,984**	**22,984**

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	12,954	6,405
5.2	Call deposits	10,030	10,030
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)**	**22,984**	**16,435**

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	92
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.

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 $92k. The payments related to the net pay of salaries, directors fees and consulting fees (inclusive of GST) 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.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	189	17
7.4	**Total financing facilities**	189	17

7.5	**Unused financing facilities available at quarter end**	172

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%

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(1,084)
8.2	Cash and cash equivalents at quarter end (item 4.6)	22,984
8.3	Unused finance facilities available at quarter end (item 7.5)	172
8.4	Total available funding (item 8.2 + item 8.3)	23,156
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	21.4

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

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 April 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.