

# Melbourne, Australia, 26 July 2021:

Genetic Technologies Limited (ASX: GTG; NASDAQ: GENE, "Company", "GTG"), a diversified Genomics and AI driven preventative health care business is pleased to provide its Quarterly Activities Report for the period ended 30 June 2021, together with the attached Appendix 4C.

# Highlights

- Revenues from customers of A\$99k in the quarter (unaudited), up from A\$6k in Q3, including receipt of first month IBX sales
- Confirmed launch of COVID-19 Risk Test by Infinity Biologix in the US
- Confirmed grant of US Patent No 11,031,098 'Computer Systems and Methods for Genomic Analysis' (ASX Announcement on 11 June 2021)
- Post quarter end acquisition of EasyDNA for US\$4 million, strategically, this direct-toconsumer acquisition provides the foundation to grow the portfolio of serious disease tests across well-established websites in 40 countries
- Strong cash balance of A\$20.8 million as at 30 June 2021 provides runway to fund commercialisation opportunities and continued product development
- Net cash used for operations of A\$2.12 million, an increase on the prior quarter (Q3 FY21: A\$1.08 million) due mainly to the increase in R&D and operating expense of A\$353k and receipt in Q3 of the R&D tax incentive receipt for \$763k
- Appointment of Carl Stubbings as Chief Commercial Officer and commencement of Mike Tonroe as Chief Financial Officer

Simon Morriss, CEO of Genetic Technologies, stated "Genetic Technologies is moving rapidly into the commercialisation of its products with the launch of the COVID-19 Risk Test in May and the post quarter end announcement of the acquisition of EasyDNA."

"This acquisition provides a direct-to-consumer platform and strong alignment with GTG's planned expansion into health and wellness testing. This alignment was critical to our decision to acquire the brand and assets of EasyDNA.

"We anticipate that as we progress our product development pipeline that there will be significant opportunity for GTG to leverage this platform to enhance the distribution and sales opportunities of our products."

# Commercialisation Update

#### Launch of COVID-19 Serious Disease Risk Test

The three-year co-exclusive licence agreement between IBX and GTG was announced on 3 March 2021 for the production, distribution, sales and marketing of GTG's COVID-19 Risk Test in the US with the product launch at the end of May 2021. Revenues (unaudited) of our COVID-19 Serious Disease Risk Test had a modest start in our first month of A\$95k.. This included the initial upfront payment of US\$50k under the IBX agreement. Sales have been sufficient to trigger the first milestone under the agreement. The regulatory environment in the US continues to evolve post quarter end. The New York State Department of Health (NYSDOH) were reviewing the emergency use status of all COVID related tests and testing collection devices. This required placing a temporary sales hold on the IBX web portal during this review period between 9 July and 23 July 2021. VAULT, our telehealth partner has remained live for other US states during this



period and the test has continued to be available to customers. We continue to closely monitor the US regulatory environment in respect of COVID-19.

# 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. With the recent inclusion of the EasyDNA acquisition the Company intends to leverage this platform to enhance the visibility and awareness of its existing products.

Additionally, GTG are engaging in sales via medical professionals for business to business (B2B) purposes and direct-to-consumer (DTC) testing with no medical supervision for products under consideration including non-medical based genetic and gut microbiome testing, subject to regulatory approval and target market.

GTG now have distribution coverage of the Australian and US geographies and have identified Europe and the UK as the next regions the company intends to enter. The Company is assessing the CE certification requirements for its products and will update the market on its progress within these regions 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 Comprehensive Risk Assessment Test (Multitest)

GTG's Polygenic Risk Score (PRS) products under development will ultimately be offered as part of the GeneType Multitest, 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. The Multitest will leverage the foundation IP granted under US Patent 7,127,355 – 'Methods for Genetic Analysis'. Recent advances in the Prostate Cancer and Melanoma Tests have identified informative polygenic risk scores that could enhance predictability with the Company intending to release initial findings by the end of CY21. The polygenic risk components of the Breast Cancer and Colorectal Cancer tests have also been improved via updated genetic risk factors.

The Multitest is designed to offer maximum flexibility for physicians administering the test. It will allow for a targeted risk assessment of single diseases providing combined assessment of hereditary cancer genes and polygenic risk or can allow for a broader "multi-test" risk assessment to provide risk profiling across multiple disease types simultaneously.

The overall strategy for the Multitest is focused on precise risk assessments for the most common preventable diseases. Future iterations of the test will include cardiovascular diseases and Type 2 diabetes along with the Company's germline hereditary cancer testing products which are currently under development. The addition of the germline hereditary testing panel will be incorporated into the GeneType Multitest ready for product launch in Q4 CY21.

# 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 hereditary tests increase coverage from 85% under standalone polygenic



risk up to 100%<sup>1</sup> of known risk coverage when combined with 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. Unaudited revenue from GeneType was A\$4k in the quarter.

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.

# Predictix by Taliaz

GTG highlighted the Predictix by Taliaz product at the General Practice Conference and Exhibition (GPCE) in Sydney in mid-May 2021 with solid feedback and are progressing discussions on partnerships to advance the distribution and sales of the product in Australia and New Zealand. In addition, the Taliaz product will be incorporated into GTG's Multitest.

#### Research and Publications

GTG continues to focus on publications of relevant content for submission to peer-reviewed journals. The Company confirms the below article, authored by GTG employees, was made available online by Cambridge University Press on 2 July 2021.

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

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.

# Post quarter end acquisition of EasyDNA

GTG signed an agreement to acquire the brand and distribution rights for EasyDNA from BelHealth for US\$4 million. The EasyDNA acquisition will provide GTG the platform to build its direct-to-consumer offerings and wellness division. This acquisition provides an established revenue stream with US\$4.63 million in unaudited revenue for CY20 and a stable outlook for future growth and the ability to leverage existing direct-to-consumer marketing avenues for future product sales.

The agreement provides for the acquisition of all brands, websites and reseller agreements associated with EasyDNA. This includes over 70 websites in 40 countries and six brand identities. EasyDNA revenue contributions are strongly weighted to five countries: Australia, UK, France, Canada and the US, where it received 68% of its CY20 revenue, with the UK as the largest market contributing 20% of total revenue. EasyDNA has current agreements with 12 NATA and associated international certified laboratories.

Simon Morriss commented, "We look forward to integrating the EasyDNA team into our business and working closely with them to continue to build upon their existing product portfolio and the brand recognition they have already achieved. EasyDNA is a leader in paternity testing and animal genomics, and their breadth of available products also extends into the important wellness category, providing multiple highly attractive growth opportunities for GTG moving forward."

<sup>&</sup>lt;sup>1</sup> Source: "An integrated clinical and genetic model for predicting risk of severe COVID-19" available at: https://www.medrxiv.org/content/10.1101/2020.09.30.20204453v1.full.pdf



GTG will be onboarding EasyDNA's existing team, retaining the skills and expertise of its employees based in Malta and Australia. This includes the retention of Kevin Camilleri, founder and CEO of EasyDNA, who will be heading up GTG's Direct to Consumer Division following the completion of the acquisition expected to occur by 31 July 2021.

For further details please refer to the ASX Release dated 19 July 2021.

# **Corporate and Financial Overview**

Cash outflows used in operating activities were A\$2,117k. Cash receipts from customers for the June quarter were A\$68k, including the initial upfront payment of US\$50k under the IBX agreement and interest received was A\$27k. Expenses incurred on a cash basis during the quarter included research and development costs of A\$777k associated with progressing the COVID-19 Risk Test and the introduction of the germline testing division. Additionally, the Company incurred A\$240k 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.

During the June quarter, net cash payments to directors was A\$93k comprising salary of A\$35k 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.

Mike Tonroe commenced as Chief Financial Officer on 15 June 2021. Mike 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.

Additionally, the Company has recently appointed Carl Stubbings to the role of Chief Commercial Officer. Carl rounds out the leadership team for GTG and will work with management and the Board to drive forward with the next stage of the commercialisation strategy. Carl is an experienced senior leader in the biotechnology and diagnostics industry with a focus on commercialisation, sales, marketing and business development.

He has considerable experience commercialising diagnostic products, both locally and globally. Based in the USA for 13 years, he served as Senior Vice President for Panbio USA Ltd and Vice-President of Sales and Marketing for Focus Diagnostics, a subsidiary of Quest Diagnostics (NASDAQ:DGX), one of the world's largest pathology laboratories. More recently he was Chief Operating Officer of ASX listed BARD1 Life Sciences having successfully facilitated the merger with Sienna Cancer Diagnostics as its CEO and Managing Director.

# Investor Webinar

The Company will provide an update on its results and recent acquisition and hold an investor webinar on Thursday 29 July 2021 at 9:30am AEST.

To participate on the quarterly investor webinar, please register at: <u>https://us02web.zoom.us/webinar/register/WN\_ntdVwrJPQkeM0XszdzUvXQ</u>

After registering, you will receive a confirmation email containing information about joining the webinar.

Authorised by the Board of Genetic Technologies Limited

Date: 26 July 2021



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

# About Genetic Technologies Limited

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

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.

**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.

**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.

**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

17 009 212 328

Quarter ended ("current quarter")

30 June 2021

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	68	89
1.2	Payments for		
	(a) research and development	(848)	(2,225)
	(b) product manufacturing and operating costs	(136)	(400)
	(c) advertising and marketing	(104)	(336)
	(d) leased assets	(163)	(455)
	(e) staff costs	(367)	(1,256)
	(f) administration and corporate costs	(592)	(3,176)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	26	62
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	1,141
1.8	Other (provide details if material)	-	-
1.9	Net cash from / (used in) operating activities	(2,116)	(6,556)

2.	Cash flows from investing activities		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(60)	(642)
	(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	-	-
	(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	(60)	(642)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	15,710
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	188
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(26)	(1,954)
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	(26)	(13,944)

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	22,984	14,214
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,116)	(6,556)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(60)	(642)

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)	(26)	13,944
4.5	Effect of movement in exchange rates on cash held	121	(57)
4.6	Cash and cash equivalents at end of period	20,903	20,903

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	10,868	12,954
5.2	Call deposits	10,035	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)	20,903	22,984

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	93
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 \$93k. The payments related to the net pay of salaries, directors fees and consulting fees (inclusive of GST) on normal commercial terms.

7.	<b>Financing facilities</b> 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)	190	9
7.4	Total financing facilities	190	9
7.5	Unused financing facilities available at quarter end		181
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.		tional financing
	<ol> <li>Secured – Bank of America, US\$25,</li> <li>Unsecured – National Australia Bank</li> </ol>	•	

8.	Estim	nated cash available for future operating activities	\$A'000	
8.1	Net ca	sh from / (used in) operating activities (item 1.9)	(2,116)	
8.2	Cash a	and cash equivalents at quarter end (item 4.6)	20,903	
8.3	Unuse	d finance facilities available at quarter end (item 7.5)	181	
8.4	Total a	available funding (item 8.2 + item 8.3)	21,804	
8.5	Estim item 8	ated quarters of funding available (item 8.4 divided by .1)	10	
	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			

# **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: 26 July 2021

Authorised by: Mike Tonroe Chief Financial Officer

#### 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.