

## 1H21 Half Year Results

**Melbourne, Australia, 26 February 2021:** Genetic Technologies Limited (ASX: GTG; NASDAQ: GENE, “Company”, “GTG”), a diversified Genomics and AI driven preventative health business is pleased to provide the half year results for the period ending 31 December 2020.

### Highlights

- Strong cash balance with pro forma cash balance of A\$24.1 million inclusive of capital raise of US\$6.56 million (A\$7.69 million) in January 2021
- Early-stage revenue of \$16k associated with sale of launched products reflecting a 2700% increase over the previous corresponding period (pcp)
- Received \$0.76 million in R&D tax incentives and COVID-19 government assistance
- Partnered with Taliax for the sale and distribution rights of PREDICTIX
- Expansion of product base into existing reimbursable segments with BRCA and Lynch Syndrome
- COVID-19 PRS test is undergoing technical validation with an expanded data set
- Findings from UK BioBank research on GTG’s predictive model outlined in the technical paper, ‘An integrated clinical and genetic model for predicting risk of severe COVID-19’ (available at: <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0247205>)
- Launch of US Consumer Initiated Testing (CIT) Platform
- Continued focus on product development and submission of publications and patents
- Post period end, announced the appointment of Simon Morriss as Chief Executive Officer on 4 January 2021

Genetic Technologies has made significant inroads over the half on its strategic objectives. The Company has further underpinned its future growth following an additional capital raise to ensure the business can execute on its objectives. Additionally, it 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 for Breast Cancer and for Colorectal Cancer.

Peter Rubinstein, Chairman of GTG, stated, “This past half has been pivotal for the Company. With the recent appointment of Simon Morriss to the role of CEO and the significant expansion of our product base we are well-positioned to move into the commercialisation phase for the business.

“Over the half, we have progressed our product suite and made the strategic decision to incorporate increased datasets in our COVID-19 PRS test. This decision resulted in a delay on the release of the test to the end of Q3 FY21 but allowed for enhanced capabilities and has had no impact on the long-term strategic opportunity for this product.

“The Company remains well funded to progress the development of its suite of products underpinned by an experienced and strengthened team able to drive forward with our stated strategy.”

## **Product Overview**

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

Genetic Technologies has continued to advance its COVID-19 PRS Test. To date GTG have:

- Analysed data on more than 6,500 infected patients following the UK biobank’s release of ~4,000 confirmed COVID-19 positive patients in November 2020.
- Enhanced the validation of the predictive capabilities of GTG’s COVID-19 PRS test, which now offers over 100% predictive accuracy than disease risk severity based on age and gender alone
- Published a paper on the COVID-19 results titled ‘An integrated clinical and genetic model for predicting risk of severe COVID-19’

GTG also intends to:

- Include additional datasets as they become available over the coming months to further enhance the predictive capabilities of the algorithm, though this will not impact the timing of commercial launch
- Upon completion of final stage testing, partner with a US based laboratory to provide the scale-up of manufacturing required to address global distribution of the COVID-19 PRS Test

Substantial effort and resources continue to be applied to the development and launch of the COVID-19 PRS Test currently scheduled for the end of March.

### *GeneType for Breast Cancer and Colorectal Cancer*

The Company’s two products in market are available via the Australian (launched in April 2020) and the US CIT platform (launched in September 2020).

- Intel labs continue to oversee patient ordering of the CIT site in the US
- Phenix Health provides oversight on the Australian based CIT site

The Company is currently capable of processing approximately 360k GeneType tests per annum by leveraging existing owned equipment with the potential to double output if required. Discussions have commenced with Medicare to enable the Company to secure a rebate for PRS tests conducted, which remains a longer-term objective and is expected to support distribution through the B2B channel.

### *Germline Testing Platform*

GTG made the decision in December 2020 to establish 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.

### *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.

### *GeneType Polygenic Risk Test Pipeline*

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.

Products in final stage development include: COVID-19 PRS Test

Products in development include: Atrial Fibrillation, Coronary Artery Disease and Type 2 Diabetes

Products in early-stage consideration include: Germline BRCA Test

## **Intellectual Property and Regulatory Approvals**

GTG's patent portfolio remains robust. GTG has submitted updates to the previously filed provisional patent 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 17 February 2021 and incorporate GTG's latest findings as outlined in the technical paper.

The provisional patent 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.

### **Commercialisation**

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.
- 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

### **Corporate and Financial Overview**

GTG received early-stage revenue of \$16k associated with sale of Genotype for Breast Cancer and Colorectal Cancer reflecting a 2700% increase over the previous corresponding period (pcp). This was predominantly driven by sales in the United States, demonstrating the larger market opportunity. Additionally, the Company received \$0.54 million in R&D tax incentives over the period and \$0.22 million in COVID-19 government assistance providing additional funding for investment into GTGs product development.

The Company is remains well capitalised with a cash balance of \$24.0 million following an in-period capital raise of US\$5.1 million and inclusive of a post quarter end capital raise of US\$6.56 million on the 25<sup>th</sup> January 2021 via a placement to several US based institutional investors.

Investment in sales and marketing and a focus on bolstering the Company's internal capabilities for commercialisation was reflected in an increase of \$0.83 million in operating loss to (\$3.47 million) (31 December 2019: loss of \$2.64 million).

Post half year end, the Company announced the appointment of Simon Morriss to the position of Chief Executive Officer. 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.

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

The Board and Management thank the team for the hard work over this past year to transition the business for this next phase. Further updates will be provided as the Company looks to commence commercialisation opportunities for the expanded product suite.

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Authorised by the Board of Genetic Technologies

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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.

**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.

**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.

**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