ASX Market Announcement



Genetic Technologies FY21 Results Turning the Corner on our Commercialisation Strategy

Melbourne, Australia, 31 August 2021: Genetic Technologies Limited (ASX: GTG; NASDAQ: GENE, "Company", "GTG"), a diversified Genomics and AI driven preventative health business is pleased to provide the financial results for the year ended 30 June 2021.

Highlights

- Revenues from customers of A\$120k including receipt of first month sales from the partnership with Infinity Biologix, an increase of A\$110k on FY20
 - Revenue in future periods will increase following the acquisition of EasyDNA on 16 August 2021
- Launched COVID-19 Risk Test in partnership with Infinity Biologix in the US
- Multi-Test development nearing completion with coverage of ~70% of all serious disease with release planned for late calendar year 2021
- Partnered with Taliaz for the sale and distribution rights of PREDICTIX, to be incorporated in GTG's Multi-Test
- Strengthened patent portfolio with the inclusion of US Patent No. 11,031,098 'Computer Systems and Methods for Genomic Analysis'
- Established a leading scientific advisory board comprising Professor Jon Emery, Professor Finlay Macrae AO, and Dr Ora K Gordan
- Strong and expanded management team following appointment of Simon Morriss, CEO;
 Mike Tonroe, CFO and post year end appoint of Carl Stubbings as Chief Commercial Officer
- Strong cash balance with pro forma cash balance of A\$17.6 million inclusive of post year end settlement of acquisition of EasyDNA
- Post year end acquisition of EasyDNA for US\$4 million (US\$2.5 million in cash and US\$1.5 million in shares), providing global platform and expansion into genomics-based 'Health and Wellness' sector in 40 countries
- Net cash used for operations of A\$6.3 million, due mainly to the increase in R&D, investment
 in Next Generation Sequencing (NGS) equipment and operating expenses as the Company
 executes on its commercialisation strategy
- Received A\$1.3 million in R&D tax incentives and COVID-19 government assistance



Genetic Technologies has undertaken a significant transformation over the year. The Company has continued to execute against strategy and underpinned its future growth following the acquisition of EasyDNA. The Company has a strong Board and management team and a solid pipeline of products in development. GTG is well-positioned with a clear platform and means for distribution of its predictive health tests.

Simon Morriss, GTG's CEO, stated "We have executed on a number of strategic milestones over the year. This included the completion and launch of the COVID-19 Risk Test, the partnership with Taliaz, the establishment of the Multi-Test product base and the post year end acquisition of EasyDNA. These initiatives have transformed the Company from a predominantly R&D base to actively commercialising its products. We are thrilled with the progress thus far and look forward to what lies ahead as we begin to embed EasyDNA and start to leverage this acquisition to drive revenue growth. We have further initiatives underway including the upcoming launch of our Multi-Test in the latter half of calendar year 2021 and continue to assess opportunities for future product innovation."

Commercialisation and Product Overview

The Company has a clear strategy on commercialisation and has the product base and distribution network to successfully execute on this strategy in the coming years. Key avenues for commercialisation of launched products 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 business 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 requiring no medical supervision for products under consideration including non-medical based genetic and gut microbiome testing, subject to regulatory approval and target market assessment.

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 European 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.

As previously outlined in the quarterly update on 26 July 2021, 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. The regulatory environment in the US continues to evolve post the year end with the New York State Department of Health (NYSDOH) 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 which has remained in place since 9 July 2021, however the review has successfully concluded, and the test is expected to be made available from 31 August. The Company continues to closely monitor the US regulatory environment in respect of COVID-19.

Intellectual Property and Regulatory Approvals

GTG was granted patent no 11,031,098 on 11 June 2021. This patent describes efficient methods for identifying variations that occur in the human genome and relating those variations to the genetic basis of disease and drug response. The methods form the basis of Genome-Wide Association Studies, particularly those focused on identifying single nucleotide polymorphisms associated with drug response ie. pharmacogenomic or pharmacogenetic markers.

GTG has submitted updates to the previously filed provisional patent for its COVID-19 Risk 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.

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 Risk Test.

Scientific Advisory Board Established

During the year, the Company established a Scientific Advisory Board (SAB) charged to advise the Board of Directors and executive leadership team on scientific matters involving product development, interactions with academic and other external research organisations, emerging concepts and industry trends, and the acquisition of technologies.

The SAB comprises Professor Jon Emery, Professor Finlay Macrae AO, and Dr Ora K Gordan, and members of the GTG executive team and meets on a quarterly basis. While additional appointments may be made in the future, the three members bring a wide range of clinical and research experience and provide GTG with coverage of both the Australian and US target markets.

GTG's SAB brings together some of the brightest minds in genomics, preventative healthcare, serious disease, and data driven research. GTG's board and management look forward to drawing on their advice and experience as we launch and develop leading technologies for individualised risk assessment of serious disease.

Corporate and Financial Overview

GTG received revenue of A\$120k associated with the agreement with IBX for the sale of the COVID-19 Risk Test and the sale of Genetype for Breast Cancer and Colorectal Cancer. Additionally, the



Company accrued A\$998k in R&D tax incentives over the period and A\$288k in COVID-19 government assistance.

The Company's cost of sales from continuing operations increased 44% to A\$361k from A\$251k in the prior year as a result of an increase in materials utilised for GeneType for Breast Cancer and Colorectal Cancer tests due to an increased number of revenue free sample tests conducted during the year.

Strategic investment in sales and marketing and a focus on investment in future growth through expanded internal capabilities and recruitments resulted in an increase to A\$5.3 million in operating expenses from A\$4.7 million in FY20. Additionally, laboratory, research and development costs increased 26% to A\$3.1 million from A\$2.5 million in the prior year. This reflected the increased development, and accelerated commercialisation of the pipeline of the new PRS tests and Germline Testing division covering the following diseases: Breast cancer, Colorectal cancer, Prostate cancer, Ovarian cancer, Melanoma, Type-2-diabetes, Coronary artery disease, Atrial fibrillation, COVID severity. Overall, the Company reported a net loss after tax of A\$7.1 million for the financial year (30 June 2020: A\$6.3 million).

The Company remains well capitalised with a pro forma cash balance of A\$17.6 million following the completion of the acquisition of EasyDNA on 16 August 2021. During the year the Company raised A\$15.9 million in gross proceeds via two placements to US based institutional investors.

The Company announced the appointment of Simon Morriss to the position of Chief Executive Officer in January 2021. This was followed with the appointment of Mike Tonroe as Chief Financial Officer in June 2021 and the post year end appointment of Carl Stubbings to the role of Chief Commercial Officer. The Company is well-positioned as well with the addition of Keven Camilleri, following the acquisition of EasyDNA, as the Head of GTG's Direct to Consumer Division.

Outlook

Commenting on the outlook, Simon Morriss stated: "We have an exceptional team working with us, a high-caliber experienced Board and SAB and a clear pathway for growth. As we enter FY22 we are confident the strategic decisions we have made over FY21 and the direction the Company is heading will deliver strong growth.

"In just a few months we have seen a significant transformation in the Company and though we have further work to do to integrate the products, platforms and team from EasyDNA we have the resources at hand to execute with confidence. We thank our shareholders for their ongoing support over the past year and look forward to reporting on our progress over FY22."

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Authorised by the Board of Genetic Technologies Limited

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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



Glossary of terms and acronyms

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.

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.

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 withs its associated morbidities and mortalities.

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.