ASX Market Announcement

Genetic Technologies 1H FY22 results

Melbourne, Australia, 24 February 2022: Genetic Technologies Limited (ASX: GTG; NASDAQ: GENE, "Company", "GTG"), a global leader in genomics-based tests in health, wellness and severe diseases, provides an overview of its half-year results for the six-months ending 31 December 2021.

Financial Performance Highlights

- Revenue from customers was A$2.05 million, compared to A$16k in the prior comparable period (pcp), following the acquisition of EasyDNA announced on 19 July 2021
- Delivered gross profit margin of 41.7%, equating to gross profit dollars of A$855k
- Strong cash balance of A$13.5 million at 31 December 2021
- A$1.2 million in receivable R&D tax incentives, up by 124% on pcp, reflecting the continued focus on development in research on genomics-based technology

Strategic & Operational Highlights

- Post period end, GTG received accreditation from NATA and CMS for the MultiTest on 17 February 2022 with commercial launch currently underway
- US patent No. US 11,257,569 granted in 'Methods of assessing the risk of developing a severe response to Coronavirus infection'
- Successful acquisition and integration of EasyDNA staff and GTG's products being available on a global platform with a significantly higher market exposure

GTG has delivered first-half revenue of A$2.05 million following the acquisition of EasyDNA. This acquisition will be the cornerstone for the Company's sales and marketing endeavours providing over 70 websites and a presence in over 40 countries. Delivering this first tranche of significant revenue demonstrates the solid and reliable revenue stream currently established from a portfolio of quality products and services. Following the launch of the MultiTest alongside other planned product expansions, the Company is well-positioned to drive further recurrent revenue growth over the coming periods.

CEO Simon Morriss added: “We have a clear commercialisation strategy, a clear pathway to bring products to market and a solid underlying portfolio of products delivering a reliable revenue stream. Following the successful acquisition of EasyDNA, we are positioned for growth and product expansion. With the recent announcement of the approval of the MultiTest earlier this week, the product launch and promotion currently underway, we are excited for what is ahead for GTG and our geneType portfolio of products.”

Strategic & Commercialisation Overview

GTG has a clear three-part commercialisation strategy to cover both the retail customer and medical professional to align with our range of non-medical and medical related genomic tests currently within the product portfolio. This encompasses Direct-to-consumer testing (DTC), Consumer initiated testing (CIT) and Medical Business to Business (B2B) distributed via both our online sales platforms and via direct engagement with distribution partners.

GTG has solid distribution coverage in Australia and the US and has identified Europe and the UK as further expansion opportunities for the Company. The Company is assessing the European CE certification requirements for its products and will update the market on its progress as further clarity on timing is obtained. An Asian market entry for relevant products will also be assessed in due course.

The direct-to-consumer (DTC) genetic testing market represents a significant growth opportunity for GTG. The total worldwide market is expected to grow from US$1.2 billion in 2020 to US$2.6 billion[1] in 2025, an increase of US$1.4 billion. The growth of the DTC segment is driven by several factors, including a broader understanding of the growing demand for disease risk analysis.

geneType Multi-Test Product Commercial Release

Post period end, NATA and CMS issued the final regulatory approval for the MultiTest, allowing commercial sales across Australia and the US. The MutiTest is designed to provide a comprehensive risk assessment on different types of commonly found cancers and serious diseases. The first phase of release covers Breast cancer, Colorectal cancer, Ovarian cancer, Prostate cancer, coronary artery disease and Type-2 Diabetes.

This risk assessment covers over 70% of the most prevalent mortalities and is designed for patients and clinicians to help improve patient outcomes in the long term. The Company plans to officially launch the MultiTest in the week of 21 February 2022.

[1] Source: www.technavio.com/report/direct-to-consumer-genetic-testing-market-size-industry-analysis&nowebp

COVID-19 Risk Test

The proprietary technology incorporated into GTG's geneType COVID-19 Risk Test was granted US patent #US11,257,569 on 22 February 2022. The granting of this patent is an important step to secure commercialisation opportunities for GTG, given the current COVID-19 prevalent environment. The COVID-19 Risk Test has a viable and sizable market, with only 75% of US residents having received at least one shot of a COVID-1 vaccine[2]. This product may improve health outcomes by providing an impetus for individuals to receive the vaccine or booster based on their personalised health risks for contracting a severe case of COVID-19.

In addition, the partnership with IBX and 1health via the 'Vitagene' platform on the US announced on 1 December 2021 continues and is expected to expand the patient distribution network for the COVID-19 Risk Test in the US. The Company has continued expanding and developing the geneType COVID-19 Risk Test, having recently completed a cross-validation study on a European data set confirming the test performance metrics. A paper describing the study has now been submitted to a peer-reviewed journal and will be released upon publication.

The geneType COVID-19 Risk Test is designed to predict disease severity in people aged 18 and older, using genetic and clinical information providing a risk score that can be used to understand a person's risk of contracting a serious case of COVID-19. In addition, employers, governments, and other public health entities may use the data to make informed decisions about disease risk, treatment options, and importantly, guiding vaccination and booster priorities.

Financial & Operation Overview

GTG's revenue predominantly related to EasyDNA and amounted to A$2.05 million (US$1.5million), compared to A$16k for the prior comparable period (pcp). GTG's gross profit for the half-year was A$855k, a gross profit margin of 41.7%, reflecting the sales volume completed for the period. We anticipate that gross profit margin will normalise at or around 50% as sales volumes increase, based on current market conditions.

The Company maintains a strong focus on driving revenue growth through investment in sales and marketing and through expanded internal capabilities and recruitments. This strategy, in conjunction with the acquisition of EasyDNA, resulted in a marginal increase in the operating loss for the half of A$0.4 million to A$3.87 million (1H21: loss of A$3.47 million) but provides an appropriate scope and scale for the business in light of the significant market opportunity and expanded business footprint.

[2] According to the Centers for Disease Control as at 15 January 2022

GTG reduced its overall general and administrative expenses by 49% to A$1.94 million (1H21: A$2.62 million) through strategic realignment of roles and capabilities within the business to reposition the business appropriately. Likewise, the Company remains focused on driving cutting edge innovation and continues to invest in laboratory, research and development costs which increased 50% to $2.13 million (1H21: A$1.06 million). This reflected the increased growth and accelerated commercialisation of its pipeline of the new PRS tests and Germline Testing division covering breast, colorectal, prostate and ovarian cancers; melanoma; type-2-diabetes; coronary artery disease; atrial fibrillation; and COVID -19 severity.

GTG is well capitalised with a cash balance of A$13.5 million, providing a strong runway to continue executing on strategy and driving further revenue growth.

Outlook

Commenting on the outlook, Simon Morriss stated: "We have successfully navigated many challenges over the past six months to deliver a solid base business from which to drive growth. With the integration of the EasyDNA platform and people within our business, we are focused on expanding and improving the brand recognition of both geneType and EasyDNA. We are committed to delivering strong growth in revenue whilst maintaining an appropriate investment in our sales and marketing and research and development efforts to increase market penetration and drive further product innovation."

"This is an exciting time to be part of the broader GTG business, and we recognise the significant contribution of the employees of GTG, both new and old, to manage through significant changes in the business and deliver solid underlying results.

We also thank our shareholders for their ongoing support and look forward to reporting on our continuing positive progress over FY22."

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Authorised by the Board of Genetic Technologies Limited

Investor Relations (AUS)
Ronn Bechler
Market Eye
M: +61 400 009 774
E: ronn.bechler@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.genetype.com

Glossary of terms and acronyms

Centers for Medicare & Medicaid Services (CMS) – the US federal authority responsible for regulating most laboratory testing performed on humans in the US through the Clinical Laboratory Improvement Amendments (CLIA) program

Clinical Laboratory Improvement Amendments (CLIA) – certification required by clinical laboratories approved by the Centers for Medicare and Medicaid Services (CMS) before human diagnostic testing

Consumer Initiated Tests (CIT) - laboratory testing 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 the consumer initiates without a physician order. The results are reported back directly to the consumer.

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 accreditation 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 delivering their products and services.