

ASX Market Announcement



Annual results – Momentum building on our commercial plans

Melbourne, Australia, 30 August 2022: Genetic Technologies Limited (ASX: GTG; NASDAQ: GENE, “Company”, “GTG”), a global leader in guideline driven genomics-based tests in health, wellness and serious disease is pleased to report annual results for the year ended June 30, 2022.

It has been an exciting 12 months focused on our commercialisation journey. We now have the most comprehensive portfolio of genetic based tests available for individuals and animals. In addition to our patented geneType polygenic based risk tests, our portfolio includes pharmacogenomics, Non-Invasive Prenatal Testing (NIPT), carrier screen testing, oncogenetic diseases, and pet care.

This year we have transformed from an R&D organisation with one polygenic risk test to an organisation with revenues anchored in 3 brands: geneType, EasyDNA and AffinityDNA.

Highlighting our commercial progress, the company announces revenues for the year ended June 30, 2022, of A\$6.674 million, an increase of 5,536% when compared with 2021.

This revenue was underpinned by our acquisition of EasyDNA in August 2021. In July 2022 we announced the acquisition of AffinityDNA which will provide additional baseline revenue growth opportunities in new markets and new channels.

Our patented geneType Multi-Risk Test is pioneering in risk assessment by combining genetic and clinical risk models with cutting-edge research. We’re leading a personalised healthcare revolution. This first in class test portfolio can predict a person’s risk in up to 70%¹ of annual mortalities and morbidities before onset. This enables us to make material progress in our mission to unlock personalised preventative healthcare. We are transforming the conversation from a one-size-fits-all model to one that is truly personalised, giving patients and physicians information they need to proactively develop and manage patient pathways according to their own risk.

In October 2021 we initiated a global re-launch of the geneType brand, followed by the commercial release of the geneType Multi-Risk Test in February 2022. The Multi-Risk Test provides six risk assessments in one test covering breast cancer, colorectal cancer, prostate cancer, ovarian cancer, coronary artery disease and Type-2 diabetes. As noted earlier, these diseases together represent approximately 70% of all annual morbidities before onset.

To support the launch of geneType and to drive the tests’ adoption we have undertaken a number of strategic initiatives.

In the US we have initiated a number of key strategies, with the appointment of an experienced VP of Business Development, John Haslet. John has considerable experience in building sales networks for the geneType brand in three key sales channels, namely:

- Independent Doctor Networks (IDNs)
- Concierge Medicine
- Payer Systems

¹ <https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm>

An important element in driving revenue through these channels is obtaining reimbursement for the geneType tests. Our first step in obtaining reimbursement was completed earlier this year with finalisation of a budget impact model (BIM). The BIM demonstrated a significant improvement in health and economic benefits and also improved patient outcomes when the geneType Breast Cancer Risk Assessment test was implemented for eligible patients. The independently developed and validated BIM was prepared by our consultants ALVA10 and shows the following benefits:

- US payers could see savings of up US\$1.4B or 3.6% annually
- 69% – 74% overall increase in women getting screened
- 6.8% - 9.2% improvement in supplemental screening frequency
- 14.8% - 8.8% drop in interval cancers
- 57% - 67% improvement in early-stage cancer detection

The importance of these results cannot be underestimated, they provide a very compelling case for US payers to reimburse the geneType Breast Cancer Risk Assessment Test. We now have more than 10 active discussions with payer groups with the goal to obtain coverage for the test.

Reimbursement of our geneType test would be a “game-changing” event for GTG. It would provide the ability to see the test widely adopted across the world’s largest healthcare market. In addition, this initiative will provide a pathway for the other tests in the Multi-Risk Test portfolio to also be reimbursed.

In Australia we have appointed a virtual sales team supported by Hahn Health, now part of global DKSH Group, to promote geneType to Australian medical practitioners. This approach has been very effective in establishing our geneType Hub concept, onboarding more than 40 practices (as of the end of August 2022). We further expanded the geneType Hub strategy through partnership with leading Obstetrics and Gynecology Specialist, Associate Professor Charles Siles. The partnership provides GTG with immediate access to more than 1,000 referring primary care physicians and 15,000 patients annually. In addition, the partnership also offers GTG with a significant opportunity in expanded Carrier and NIPT Testing.

In May 2022, we launched the rebranded EasyDNA and commenced the rebuild of the websites. Our team have continued to look worldwide for unique growth initiatives and launched a number towards the end of the year:

- Carrier Testing and Non-Invasive Prenatal Tests (NIPT) into Europe
- Partnering in India with stud farms extending paternity into the equine industry
- DNA storage solution in GTG's NATA approved facility

Our scientific team have been very busy. In the last year the company has had 10 patents granted and 5 new provisional patents filed. The team has four publications published in peer reviewed journals with a further three papers submitted and under review. In addition, we continue to work on the optimisation of our existing tests. An important example of optimisation of our existing test was a study of 200,000 participants which we presented late last year at the San Antonio Breast Cancer Symposium. This work validated the geneType Breast Cancer Risk Assessment Test model with an expanded panel of 313 Single Nucleotide Polymorphisms (SNPs). In addition, the scientific team has been working on expanding the number of diseases the Multi-Risk Test can predict.

During the coming financial year, we expect to add melanoma, type 2 diabetes and pancreatic cancer to the portfolio.

The quality of the work being undertaken by Dr Allman's team is highlighted by the strength of collaborations that GTG has built, including:

- Professor Bernard Rosner. Channing Division of Network Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston, Massachusetts, USA – Principal Investigator of the Nurses' Health Study (International expert in Biostatistics and breast cancer epidemiology)
- Professor Graham Colditz. Deputy Director, Institute for Public Health. Washington University School of Medicine, St. Louis, Missouri (International expert in Biostatistics and breast cancer epidemiology)
- Professor Jon Emery, Professor of Primary Care Cancer Research at the University of Melbourne, and the Victorian Comprehensive Cancer Centre
- Professor John Hopper, Professorial Fellow at the Centre for Epidemiology and Biostatistics in the School of Population Global Health, Melbourne University

The Australian laboratory expanded their capabilities by gaining NATA accreditation for six polygenetic risk score tests and a new GSA pipeline. The laboratory also received US CMS - CLIA certification for the same six polygenetic risk tests and GSA pipeline. Finally, our regulatory team received ARTG notification from the Therapeutic Goods Administration (TGA) for the geneType Multi-Risk test.

In the coming year we are focussed on four key areas:

- Driving revenue and commercialisation of the geneType suite of tests, expanding on the commencement of the initiatives outlined
- Driving growth in the EasyDNA and AffinityDNA brands with new tests, new markets and new channels
- Continuing the demonstration of the clinical utility of the geneType tests with our highly engaged scientific and medical advisors and robust patent and publication strategy
- A focus on innovation with the introduction and assessment of new divisions

We have the most comprehensive portfolio of testing available; we now offer more than 50 tests across 14 categories with future revenues anchored in our three brands; geneType, EasyDNA and Affinity DNA.

We would like to thank you for your continued support. Our company is uniquely placed to seize a multi-billion-dollar opportunity in a very high profile and rapidly growing market.

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Authorised for release by the board of directors of Genetic Technologies Limited

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About Genetic Technologies Limited

Genetic Technologies Limited (ASX: GTG; Nasdaq: GENE). A global leader in genomics-based tests in health, wellness and serious disease through its geneType, EasyDNA and AffinityDNA brands. GTG lead the most comprehensive portfolio of genetic tests from Carrier screening and NIPT to the advanced predictive testing and assessment tools to help physicians to improve health outcomes for people around the world. The company's Polygenic Risk Scores (PRS) platform is a proprietary risk stratification platform developed over the past decade integrating clinical and genetic risk delivering actionable outcomes from physicians and individuals. Leading the world in risk prediction in Oncology, Cardiovascular and Metabolic diseases. Genetic Technologies continues to develop a pipeline of risk assessment products. For more information, please visit www.genetype.com