

Personalised Predictive Genomics

Genetic Technologies (GTG) is a molecular diagnostics company offering a portfolio of guideline-driven genomic-based tests globally. GTG has developed a suite of patented genomic-based predictive screening and assessment tools aimed to help physicians better stratify individuals at increased risk of developing common and complex disease before onset. This creates a pathway to proactively manage patient health with personalised care plans while avoiding unnecessary interventions. The commercial launch of the innovative geneType Multi-Risk Test represents the culmination of 10 years of research and heralds a new era for GTG. Recent acquisitions of direct-to-consumer companies EasyDNA and AffinityDNA add new revenue streams, diversify technology platforms and expand distribution channels globally. As such, GTG is primed to win a meaningful share of the emerging genetic testing market given its broad genomic product portfolio targeting multiple segments.

GeneType Platform – A Comprehensive Risk Score

GTG's geneType platform integrates genetic information with traditional clinical risk factors to predict a person's chance of developing disease in the future via patented algorithms. Tests use patient genetic variants known as SNPs to calculate a Polygenic Risk Score (PRS), which when combined with traditional clinical and familial risk factors produce a Comprehensive Risk Score (CRS). The CRS indicates a patient's predisposition to developing the disease in the future (5-year risk and lifetime risk), and can be used to inform clinical decisions, improve current screening techniques and indicate further screening (although it cannot detect disease and thus is not a screening tool per se).

The geneType platform currently covers 6 major diseases (breast cancer, colorectal cancer, ovarian cancer, prostate cancer, coronary artery disease and type 2 diabetes) with another 3 diseases (melanoma, pancreatic cancer, atrial fibrillation) expected to be added by end-CY22.

Building on First-Mover Advantage in Breast Cancer

GeneType for breast cancer supersedes GTG's earlier first-in-class BREVAGen™ and successor BREVAGEN*plus* breast cancer risk assessment products. The new improved test incorporates multiple additional clinical risk factors and predicts the risk of developing breast cancer over 5 years and the remaining lifetime (in absolute terms). In our opinion, GTG's first-mover advantage in breast cancer risk assessment, clinical supporting data and substantial market opportunity make geneType for breast cancer fundamental to GTG's investment case and a proof of concept for the geneType platform overall. Health economic benefits of geneType for breast cancer should support reimbursement coverage in the US which, if achieved, could be a major catalyst for adoption.

CLIA-Certified Laboratory Supports Path to Market

GTG's Melbourne-based laboratory is CLIA certified, which supports rapid new product development and allows it to market products directly into the US.

Valuation

We value GTG at A\$118m or A\$0.012/share (diluted), using DCF methodology on free cash flow and based on 9,220m shares on issue and 265m options respectively. Risks include IP, shareholder dilution, competition and management retention.



Genetic Technologies (GTG) is an ASX-listed molecular diagnostic company focused on disease risk prediction. The company uses polygenic markers of risk combined with clinical factors to predict risk of disease.

The introduction of geneType Multi-Risk test incorporating – geneType for breast cancer for non-hereditary breast cancer and geneType for colorectal cancer – along with integration of recently acquired DNA based products underpin a broad and complementary portfolio of genomic based tests creating a significant competitive advantage. The company operates in the USA, Europe, and Asia Pacific under various revenue models.

<https://www.genetype.com>

Stock	GTG.ASX; NASDAQ: GENE
Price	A\$0.004
Market cap	A\$37m
Valuation	A\$0.012/share (diluted)

Company data

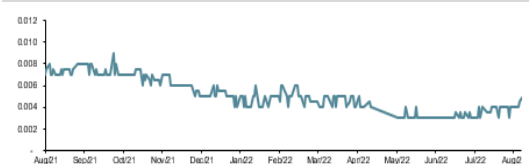
Cash on hand (30 June 2022)	A\$11.7m
Shares on issue	9,234m
Options	265m

Potential near term catalysts

Coverage from payer groups in the US for geneType tests – B2B/CIT

Relaunch of new EasyDNA ecommerce platform

GTG share price (A\$)



Source: FactSet.

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Financial Summary

Genetic Technologies Limited GTG						GTG-AU
Year end 30 June, AUD unless otherwise noted						
MARKET DATA						
Price	\$	0.004				
52 week high / low	\$	0-0.01				
Valuation	\$	0.01				
Market capitalisation	\$m	36.9				
Shares on issue (basic)	m	9234.0				
Options / rights	m	265.0				
Other equity	m	0.0				
Shares on issue (diluted)	m	9499.0				
12-MONTH SHARE PRICE PERFORMANCE (AS)						
INVESTMENT FUNDAMENTALS						
Reported NPAT	\$m	(6.3)	(7.1)	(7.1)	(2.0)	0.3
Underlying NPAT	\$m	(6.3)	(7.1)	(7.1)	(2.0)	0.3
Reported EPS (diluted)	¢	(15.0)	(82.8)	(77.3)	(0.0)	0.0
Underlying EPS (diluted)	¢	(15.0)	(82.8)	(77.3)	(0.0)	0.0
Growth	%		452.2%	-6.6%	-100.0%	-114.2%
Underlying PER	x	nm	nm	nm	nm	128.3
Operating cash flow per share	¢	(0.1)	(0.1)	(0.1)	(0.0)	0.0
Free cash flow per share	¢	(0.1)	(0.1)	(0.1)	(0.0)	0.0
Price to free cash flow per share	x	nm	nm	nm	nm	75.9
FCF Yield	%	nm	nm	nm	nm	1.3%
Dividend	¢	0.0	0.0	0.0	0.0	0.0
Payout	%	0.0%	0.0%	0.0%	0.0%	0.0%
Yield	%	0.0%	0.0%	0.0%	0.0%	0.0%
Franking	%	0.0%	0.0%	0.0%	0.0%	0.0%
Enterprise value	\$m	23.2	16.2	25.9	27.6	27.1
EVEBITDA	x	(3.7)	(2.4)	(3.9)	(17.9)	58.3
EV/EBIT	x	(3.7)	(2.3)	(3.6)	(13.7)	89.9
Price to book (NAV)	x	2.1	1.7	2.2	2.6	2.5
Price to NT A	x	2.2	1.7	2.3	2.6	2.6
KEY RATIOS						
EBITDA margin	%	nm	nm	nm	nm	2.1
EBIT margin	%	nm	nm	nm	nm	1.3
NPAT margin	%	nm	nm	nm	nm	1.3
ROE	%	nm	nm	nm	nm	2.0
ROA	%	nm	nm	nm	nm	1.5
Net tangible assets per share	\$	0.0	0.0	0.0	0.0	0.0
Book value per share	\$	0.0	0.0	0.0	0.0	0.0
Net debt/(cash)	\$m	(13.7)	(20.7)	(11.1)	(9.3)	(9.8)
Interest cover/ (EBIT/net interest)	x	nm	nm	nm	nm	(21.5)
Gearing (net debt/EBITDA)	x	nm	nm	nm	nm	nm
Leverage (net debt/(net debt + equity))	x	nm	nm	nm	nm	nm
DUPONT ANALYSIS						
Net Profit Margin	%	nm	nm	nm	nm	1.3
Asset Turnover	x	0.0	0.0	0.3	0.8	1.2
Return on Assets	%	nm	nm	nm	nm	1.5
Leverage	x	1.1	1.1	1.3	1.3	1.3
Return on Equity	%	nm	nm	nm	nm	2.0
KEY PERFORMANCE INDICATORS						
GenType Sales EasyDNA and AffinityDNA Sales GenType and US Payers						
HALF YEARLY DATA						
Product revenue	\$m	0.1	2.1	4.7	7.3	7.3
Operating expenses	\$m	(4.9)	(7.1)	(2.1)	(9.1)	(9.1)
EBITDA	\$m	(4.1)	(3.8)	4.7	(0.8)	(0.8)
EBIT	\$m	(4.2)	(3.9)	4.2	(1.0)	(1.0)
PBT	\$m	(4.2)	(3.9)	4.2	(1.0)	(1.0)
Reported NPAT	\$m	(4.2)	(3.9)	4.2	(1.0)	(1.0)
PROFIT AND LOSS						
Product revenue	\$m	0.0	0.1	6.8	14.5	22.6
Other income	\$m	1.1	1.6	2.8	1.6	1.6
Operating expenses	\$m	(7.4)	(8.7)	(15.9)	(18.1)	(23.9)
EBITDA	\$m	(6.2)	(6.9)	(6.6)	(1.5)	0.5
Depreciation & Amortisation	\$m	(0.1)	(0.2)	(0.6)	(0.5)	(0.2)
EBIT	\$m	(6.3)	(7.1)	(7.2)	(2.0)	0.3
Interest expense	\$m	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)
Pretax Profit	\$m	(6.3)	(7.1)	(7.2)	(2.0)	0.3
Tax expense	\$m	0.0	0.0	0.0	0.0	0.0
Reported NPAT	\$m	(6.3)	(7.1)	(7.1)	(2.0)	0.3
Weighted average diluted shares	m	4,155.0	8,544.2	9,220.3	9,220.3	9,220.3
GROWTH PROFILE						
Revenue	%	(61.2)	1,122.2	5,536.3	114.0	55.5
EBITDA	%	6.3	10.9	(4.0)	(76.7)	(130.2)
EBIT	%	4.6	12.6	1.7	(72.0)	(115.0)
Reported NPAT	%	(2.0)	12.4	0.8	(71.6)	(114.2)
BALANCE SHEET						
Cash	\$m	14.2	20.9	11.7	10.0	10.5
Receivables	\$m	0.8	1.1	2.4	2.5	2.7
Inventory	\$m	0.1	0.1	0.4	0.4	0.4
Other	\$m	0.1	0.2	0.2	0.2	0.2
Current assets	\$m	15.2	22.2	14.7	13.1	13.8
Right-of-use assets	\$m	0.4	0.2	0.6	0.5	0.4
PPE	\$m	0.0	0.5	0.3	0.3	0.3
Other	\$m	0.0	0.1	5.1	5.0	4.9
Non current assets	\$m	0.4	0.7	6.1	5.8	5.5
Total assets	\$m	15.6	23.0	20.8	18.9	19.3
Trade and other payables	\$m	0.7	0.8	2.1	2.2	2.3
Lease liabilities	\$m	0.2	0.0	0.8	0.8	0.8
Other	\$m	0.4	0.6	0.9	0.9	0.9
Current liabilities	\$m	1.4	1.4	3.8	3.9	4.0
Lease liabilities	\$m	0.2	0.0	0.4	0.4	0.4
Other liability	\$m	0.1	0.0	0.2	0.2	0.2
Non current liabilities	\$m	0.2	0.0	0.6	0.6	0.6
Total liabilities	\$m	1.6	1.4	4.4	4.5	4.6
Net assets	\$m	14.0	21.5	16.4	14.4	14.7
Share capital	\$m	140.1	153.6	155.1	155.1	155.1
Retained earnings	\$m	(136.0)	(143.1)	(150.2)	(152.2)	(151.9)
Other	\$m	9.9	11.0	11.5	11.5	11.5
Total equity	\$m	14.0	21.5	16.4	14.4	14.7
CASH FLOW						
Net loss for period	\$m	(6.3)	(7.1)	(7.2)	(2.0)	0.3
Depreciation & Amortisation	\$m	(0.1)	(0.2)	(0.6)	(0.5)	(0.2)
Changes in working capital	\$m	0.9	(0.4)	0.2	(0.0)	(0.0)
Other	\$m	(0.3)	1.4	1.9	0.9	0.5
Operating cash flow	\$m	(5.7)	(6.3)	(5.7)	(1.6)	0.6
Payments for PPE	\$m	(0.0)	(0.7)	(0.1)	(0.2)	(0.2)
Other	\$m	0.1	0.0	(3.4)	0.0	0.0
Investing cash flow	\$m	0.1	(0.7)	(3.5)	(0.2)	(0.2)
Equity	\$m	21.8	15.9	0.0	0.0	0.0
Lease liability payments	\$m	(0.2)	(0.3)	(0.3)	0.0	0.0
Other	\$m	(3.2)	(2.0)	(0.0)	0.0	0.0
Financing cash flow	\$m	18.4	13.7	(0.3)	0.0	0.0
Cash year end	\$m	14.2	20.9	11.7	10.0	10.5
Free cash flow	\$m	(5.6)	(7.0)	(9.1)	(1.7)	0.5

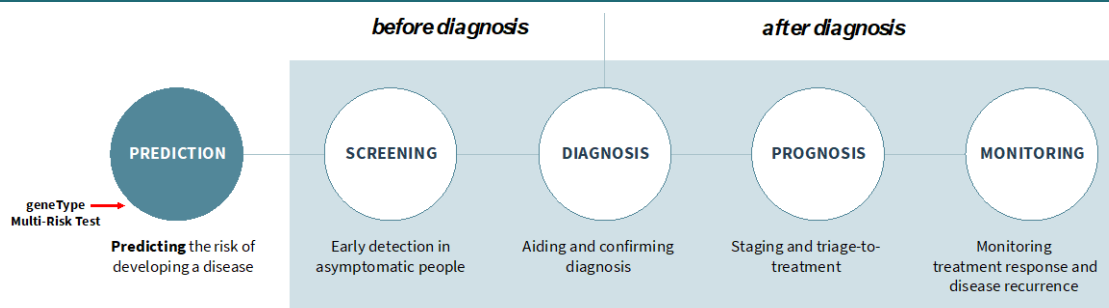
Source: GTG, MST Access.

Thesis: Using Genetic-Integrated Clinical Risk for Predicting Disease

Company Profile: Saliva-Based Genomic Testing for Common and Complex Diseases

Genetic Technologies (GTG) is an ASX- and Nasdaq-listed molecular diagnostic company and a leading provider of genomic tests for common and complex diseases. Its tests analyse scientifically validated genetic variances in DNA known as single nucleotide polymorphisms (SNPs) in conjunction with clinical and familial risk factors. GTG's lead product is a patented and regulatory approved multi-risk test covering 6 (moving to 9 by end-2022) of the most common serious diseases causing over 70% of all mortality and morbidity globally. Branded 'geneType', the internally developed test integrates an individual's familial, clinical, and genetic information to help assess predisposition to disease. The company's genomic test product portfolio uses DNA sequencing and array-based technologies. GTG is headquartered in Melbourne, Australia where it operates its NATA-accredited and CLIA-certified laboratory.

Exhibit 1: Assessing risk proactively with the geneType Multi-Risk Test allows patients to manage their health and make informed decisions **before** developing a disease or condition



Source: MST Access.

Company history

GTG was founded in 1989 and listed on the ASX in 2000 and the NASDAQ in 2005. In 2007, identification of clinically validated SNPs, each with an associated small relative risk of breast cancer, led to the development of GTG's first commercially available genetic risk test for sporadic breast cancer, BREVAGen™. (Sporadic breast cancer occurs in people with no family history of that cancer and with no inherited change in their DNA that would increase their risk for it, making this kind of cancer difficult to predict with traditional methods.) Launched in 2011, BREVAGen™ was a first-in-class, clinically validated risk assessment test for non-hereditary breast cancer. The next (and now superseded) iteration of the test, BREVAGen^{plus}, combines 77 SNPs identified from multiple large-scale genome-wide association studies (GWASs) and subsequently tested in nested case-control studies utilising Caucasian, African American and Hispanic patient samples.

In 2019, GTG began development of its recently launched geneType for breast cancer test which uses array technology to identify relevant SNPs which are combined with additional clinical factors to produce a Comprehensive Risk Score (CRS) for disease. The test provides a 5-year and lifetime assessment of the patient's risk of developing breast cancer. The test has been expanded into other cancers and complex disease and is designed to act as an initial screening technique.

GTG has acquired two direct-to consumer e-commerce DNA testing businesses: EasyDNA (2021), with over 70 websites in 40 countries and 6 brand identities; and AffinityDNA (2022), with a variety of DNA tests including lifestyle, health, and wellbeing genomics-based tests, paternity testing, plus animal testing relating to allergies and tolerances via online marketplaces, including Amazon.

Market Opportunity: Multiple Possibilities, but Breast Cancer Has First-Mover Advantage

Broad portfolio of tests, from the simplest consumer-initiated products to complex medical B2B

The company has a diverse array of tests that fall into three categories: (1) **direct-to-consumer testing**, which largely involves simple tests that do not require medical supervision; (2) **consumer-initiated testing**, done with the supervision of a medical practitioner; and (3) **medical business-to-business (B2B)**, which must be requested by a medical professional. We view this array of tests as broad and highly complementary, supporting economies of scale and creating significant barriers to entry.

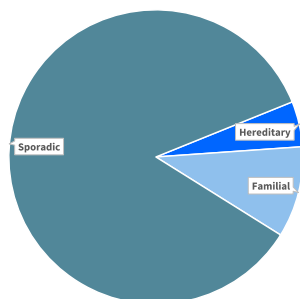
Breast cancer opportunity (in medical B2B category) looks most promising; provides proof of concept

Notwithstanding the multiple opportunities afforded by geneType's disease coverage and the new direct-to-consumer offerings, we see the strongest evidence of clinical utility in breast cancer. Given the company's first-mover advantage in breast cancer testing, substantial clinical supporting data and the substantial market opportunity, we view this product as the cornerstone of the investment case and use this product to illustrate the science and workflow for the overall platform. As such, we see geneType for breast cancer as representing proof of concept for the geneType platform.

The 313 SNPs that generate the product's Polygenic Risk Score were identified from over 500,000 SNPs in multiple GWASs involving over 50,000 women and validated in independently conducted studies. As such, strong evidence supports the genomic risk variants used to calculate PRS in the geneType risk model for breast cancer risk assessment.

According to the American Cancer Society, 1 in 8 women will develop breast cancer during their lifetime. Current clinical guidelines qualifying women to be screened for BRCA testing, or other hereditary cancer syndromes largely revolve around cancer family history. However, 85% of breast cancers are sporadic for which no causative mutation is known or related to hereditary or familial history (see Exhibit 2). As such, geneType's integrated approach represents an evolution on current risk model gold standards that could help with the large cohort of sporadic breast cancer patients.

Exhibit 2: Sporadic breast cancer accounts for 85% of all cases



Hereditary: only 5% of cases – develop with a clear hereditary cause

Familial: 10% of cases – have no known pathogenic variant

Sporadic: remaining 85% of cases –

may benefit from geneType genetic-integrated clinical risk approach

Source: GTG (<https://genetype.com/for-medical-practitioners/breast-cancer-predictive-test/>).

Valuation

We value GTG at A\$118m or A\$0.012 per share (diluted), using discounted cash flow (DCF) methodology on free cash flow and based on 9,220m shares on issue and 265m options respectively. This represents an upside to the current share price of approximately 192%. Key DCF inputs are beta of 1.25, WACC of 12.5% and terminal growth rate of 2%. We think DCF methodology allows for more granular modelling of accumulated tax losses and best captures the cash flow generation potential of the business over time. Our fair value per ASX-listed share (diluted) for GTG (GTG.ASX) equates to US\$5.38 per Genetic Technologies Limited Sponsored ADR listed on NASDAQ (GENE.US).

Risks and Sensitivities

Risks include but are not limited to intellectual property and patent challenges, shareholder dilution, competition and retaining management risks. As developers of Laboratory Developed Tests or LDTs, the company is susceptible to changes in regulatory oversight by the FDA or NATA. Similarly, loss of CLIA certification of the Melbourne facility would have a major impact on operations.

Company Outlook – Building a Broad-Based Genomics Business

GTG's acquisition of EasyDNA and AffinityDNA, combined with the recent launch of its geneType Multi-Risk Test, has delivered critical mass, and delivered significant benefits to the company:

- **portfolio breadth:** the company now has a well-diversified, complementary portfolio of genomic tests targeting multiple applications (including niche) across multiple markets
- **geographic reach:** the integration of EasyDNA and AffinityDNA expands the company's reach globally across North America, Europe, and Asia Pacific.

As such, the investment case for GTG relies on adoption and gaining commercial traction for both its recently acquired products and the geneType Multi-Risk Test in various sales channels. Notwithstanding the new direct-to-consumer 'lifestyle' products brought in through the acquisition of EasyDNA and AffinityDNA, GTG is focused on leveraging its intellectual property in the field of genomic testing for clinical applications. Specifically, GTG is developing predictive testing and risk assessment tools using genomic techniques to help physicians proactively manage patients' health, and to assist individuals who seek to initiate their own health and wellness journey.

Products: Diverse Mix of 3 Divisions Based on DNA Sequencing, Array Tech Platforms

Direct-to-consumer testing (DTC) – DNA sequencing

This segment relates to laboratory testing that is initiated by the consumer without a physician order. The results are reported back directly to the consumer.

Consumer-initiated testing (CIT)

This is laboratory testing that is initiated by the consumer without a physician order but reviewed and communicated back to the consumer via a physician.

Medical business-to-business (B2B)

This segment involves laboratory testing that is initiated by the physician and reviewed and communicated back to the consumer via a physician.

Exhibit 3: Product categories, product list and partnership information

Category	Products	Partners
Direct to Consumer Testing (DTC) with no medical supervision	EasyDNA Ancestry Paternity Health & Wellbeing Pharmacogenetics	Agreements with 12 laboratories in North America, Asia Pacific and Europe
	AffinityDNA Animal Drug Testing Relationship Covid-Antigen Tests DNA Storage	
Consumer Initiated Testing (CIT) available through medical practitioners only	geneType Health & Wellbeing - Nutrition Oncology - Multi-Test Cardiovascular MultiTest Metabolic-Multi-Test COVID Risk Test Pharmacogenomics	LimsABC InTeleLabs in the US
	geneType Oncology - GTG NIPT Cardiovascular Prenatal Clinical & Molecular Metabolic Taliaz Predictix	
Medical Business to Business (B2B) healthcare professional requested test		A plan curated for: Payers/Insurers, Primary Care Physicians, Specialists, Surgeons, Allied Health

Source: GTG.

Flagship Product: geneType Platform and Predictive Risk Assessment – Comprehensive Risk Score for Complex Diseases

In February 2022, GTG received simultaneous approval, with NATA accreditation and CLIA certification, respectively, enabling the commercial launch of the geneType Multi-Test in Australia and the US. The company is now pursuing a two-stage roll out of the test with Phase 1 covering six diseases: breast, colorectal, prostate, and ovarian cancers, and coronary artery disease and Type-2 diabetes all in one test sample. These diseases account for ~50% of annual morbidities in the US. This product is marketed to both the medical B2B and consumer-initiated test segments.

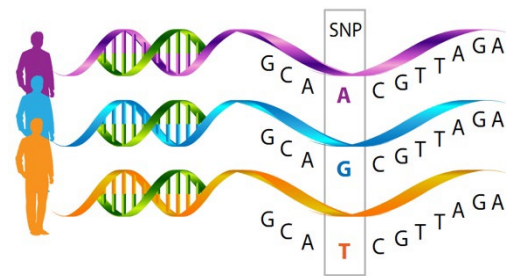
History of the geneType platform

Launch of the geneType brand in 2021, followed by the commercial launch of the geneType Multi-Risk Test in February 2022, is a culmination of 10 years of research and heralds a new era for GTG. Building on the legacy BREVAGen*plus* product, the company's new geneType platform also checks for relevant and independent risk-associated SNPs (see 'The basics of genomic testing' below) but incorporates multiple additional risk factors designed to increase the test's predictive accuracy and better stratify patient subsets, thus enabling patients and their clinicians to develop long-term health plans.

The basics of genomic testing:

How identified mutations (SNPs) can inform medical treatment, and how geneType goes further

How are genetic variants discovered? Genome-wide association studies (GWASs) are huge undertakings to determine the genetic code for large populations. In particular, the 1000 Genomes Project, launched in 2008 and still one of the most comprehensive genome initiatives, created a public catalogue of human genetic variation. The project allowed 2,500 genomes to be sequenced from around 25 global populations and created reference standards in multiple ethnicities.



How are disease-associated variants identified? Researchers can identify significant aberrations ('variants') in DNA/RNA and benchmark them against the larger dataset. Single-nucleotide polymorphisms (SNPs, pronounced 'snips') are base-pair variations at specific locations in the genome – a single change in a building block (nucleotide) of DNA/RNA (see image, from standardofcare.com). To be defined as an SNP, the variant must occur in at least 1% of the population. Many are harmless – almost 1 out of every 1,000 nucleotides contains an SNP. However, SNPs become particularly important in genetic testing when they are disease associated. GWASs test hundreds of

thousands of genetic variants across many genomes to find those statistically associated with a specific trait or disease. The SNP can then be validated in other population cohorts and prospective studies.

How has this information informed treatment until now? Some SNPs have been found to have an association (of various degrees of significance) with disease. These variants may create varying risk levels for disease, from rare, highly penetrant mutations (such as those in BRCA1 and BRCA2) to variants conferring more moderate risks. This information can be used to identify increased risks of health problems, choose treatments, or assess responses to treatments.

What does geneType add to this process? The geneType test uses this information in a more sophisticated way, measuring genetic-integrated clinical risk by considering traditional risk factors in tandem with genetic risk. The test first quantifies the correlation between any identified SNP and a disease (established by evidence of association derived from large population studies) and then weights the effects of the various disease-associated SNPs to derive a single measure of genetic risk: the Polygenic Risk Score (PRS). The PRS is considered alongside traditional risk assessment factors (familial risk and clinical risk) to generate the test's final, bottom-line risk assessment: the Comprehensive Risk Score (CRS).

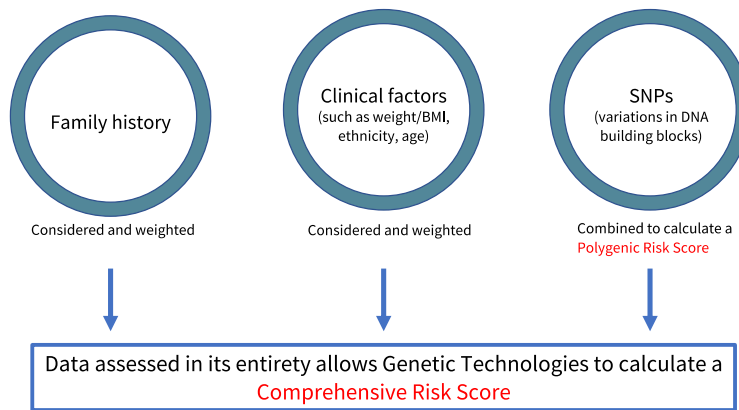
The geneType clinical workflow

Patient saliva is collected and sent to the laboratory where an SNP genotyping assay is conducted using microarray technology (600,000 probes) to produce a genetic risk score reflecting degree of variations compared to reference controls. This is combined with clinical assessment of the patient based on risk-associated clinical factors to produce a single number representing the patient's risk of developing the disease in absolute terms over a future defined period.

Benefits of the integrated geneType risk prediction model

Stratifies patients for optimal care: The novel aspect of the geneType platform is how, using a proprietary algorithm, it integrates a Polygenic Risk Score (PRS) based on SNP-related genetic information with traditional clinical and familial risk factors to generate a Comprehensive Risk Score (CRS). The CRS aims to predict a person’s future chance of developing a disease. While the test can be used as a first-line tool to indicate increased screening, it is not capable of disease detection and is therefore not a screening tool per se. Rather, geneType is marketed as a tool for identifying at-risk adults and helping healthcare professionals stratify patients and apply supplemental screening and risk-reduction options, helping determine which patients to direct into downstream standards of care, including screening and proactive health plan management.

Exhibit 4: Components of GTG’s genetic-integrated clinical risk model – the geneType Multi-Risk Test



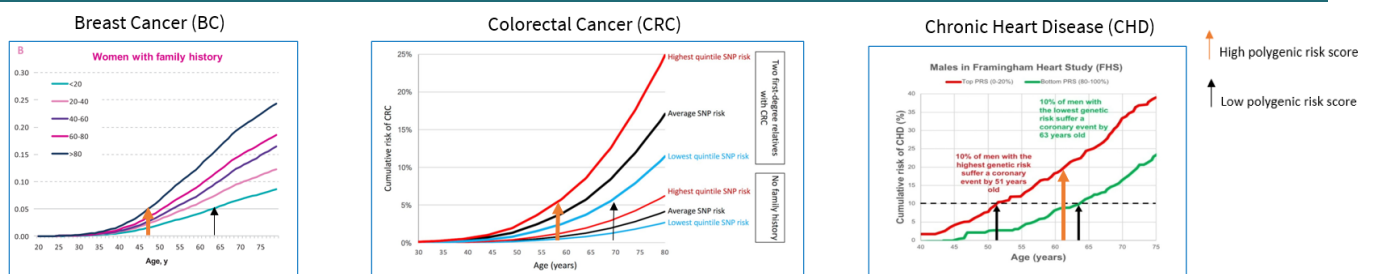
Source: GTG. NB: environmental factors included when significant (e.g., smoking status, alcohol usage, sunbed usage, HRT usage.)

CRS provides actionable outcomes for proactive patient management, and helps prevent unnecessary interventions:

The CRS reflects, for most current tests, a short- and long-term (5-year and lifetime) risk of disease. The CRS is an absolute number that is directly comparable to values used in existing medical guidelines, and can be compared to these guidelines to indicate additional screening or preventive options.

Independent genomic studies validating the design features of geneType, and using data from large genome banks, showed high-risk (high-PRS) patients could be identified 10–15 years earlier than those with low risk (see Exhibit 5 for an illustration of these results). Such early identification could provide patients with valuable additional time for interventions such as preventative medication and lifestyle changes. Additionally, determining that a patient does not have a high risk, when genetic, familial and clinical factors are all taken into consideration, can potentially avoid the emotional, physical and financial cost of excessive intervention. For example, current breast cancer interventions such as early screening and endocrine risk-reducing medication can lead to overdiagnosis, increased cost and side effects.¹

Exhibit 5: Actionable risk of serious disease identified 10–15 years earlier for high-PRS individuals vs. low-PRS individuals (lines show stratified groups by PRS, indicating that those with a higher PRS did in fact develop disease more frequently)



Source: GTG (Cumulative risk profiles for three of GTG’s targeted disease applications – various sources).

¹Mavaddat, N et al, *JNCI J Natl Cancer Inst* (2015) 107(5): djv036, doi: 10.1093/jnci/djv036.

The Most Promising geneType Test with Head Start and Strong Health Economics

Strategy: building on a first-mover advantage in breast cancer – BREVAGen™ led the way

The launch of geneType for breast cancer represents the culmination of over 10 years of research by GTG following the launch of BREVAGen™, considered first in class at the time of its release in 2011. Independent research conducted since the release of BREVAGen™ has both validated GTG's genetic-integrated clinical risk model approach and identified multiple other disease opportunities for risk prediction applications.

Product features: geneType for breast cancer

GeneType for breast cancer combines the key risk factors for breast cancer (family history, mammographic breast density and single nucleotide polymorphisms – SNPs) in a proprietary algorithm to provide an integrated 5-year and lifetime risk score for the patient.

The geneType for breast cancer model incorporates the following factors:

- age and menopausal status
- ethnicity
- number of affected female first-degree relatives and age of youngest affected first-degree relative
- number of affected second-degree relatives
- BIRADS²/percent mammographic breast density
- BMI (calculated using height and weight)
- 313 SNPs to generate the Polygenic Risk Score

Medical practitioners ordering the test receive a detailed report (see Exhibit 6) with the results of the analysis, including the short-and long-term Comprehensive Risk Score and the Polygenic Risk Score, along with commentary.

Exhibit 6: Snapshots from reports to medical providers from geneType analysis, showing how risk is communicated

Breast Cancer Risk Assessment Test Report

GeneType for Breast Cancer

geneType Oncology

Laboratory Accession Number: [REDACTED] Patient Name: [REDACTED] Ordering Medical Provider: [REDACTED]
 Date of Specimen Collection: [REDACTED] Date of Birth: [REDACTED]
 Date of Laboratory Receipt: [REDACTED] Patient Address: [REDACTED]
 Date of Report: [REDACTED]

This patient is at an INCREASED risk of breast cancer

3.50% Patient's 5 year risk **14.22%** Patient's Lifetime risk

5 Year Risk

Lifetime Risk

*The average risk is based on the same age, biological gender and race/ethnicity as the patient from the general population.

Interpretation

This patient has a 14.22% chance of developing breast cancer within her remaining lifetime up to age 90 years. This is considered an average risk because it is below the 20% threshold defined by the American Cancer Society and other medical associations.

This patient has a 3.50% chance of developing breast cancer over the next 5 years which is considered an increased risk. This is higher than the actionable threshold of 1.67% as defined by NCCN and higher than 3% as defined by USPSTF.

The patient should continue following general population breast screening protocols at a minimum, regardless of their estimated risk score. Also note that the risk scores are patient-specific and cannot be used to estimate risk in relatives. Furthermore, these results should be interpreted by a healthcare provider in the context of the patient's full clinical history.

Patient Name: [REDACTED] Date of Birth: [REDACTED] Laboratory Accession Number: [REDACTED]

Clinical Responses
as provided on the request form

Does the patient have a medical history of any breast cancer or ductal carcinoma in situ (DCIS) or lobular carcinoma in situ (LCIS)?* **No**

Does the patient have a mutation in either the BRCA1 or BRCA2 gene, or a diagnosis of a genetic syndrome that may be associated with elevated risk of breast cancer? **No**

What is the patient's age? **67**

What is the patient's race/ethnicity? **non-Hispanic White**

What is the patient's height? **6'1" ft**

What is the patient's weight? **201 lbs**

How many first-degree relatives does the patient have who have had breast cancer? (mother, sister, daughter) **Unknown**

What was the age of the youngest first-degree relative when they were diagnosed with breast cancer? **N/A**

How many second-degree relatives does the patient have who have had breast cancer? (aunts, nieces, grandparents, grandchildren, half-siblings, and double cousins) **1**

What is the patient's menopausal status? **peri-menopausal**

Has the patient ever had a breast mammogram? **Yes**

What is the patient's reported mammographic breast density? **N/A**

*please note: this risk assessment does not test for any of the aforementioned genetic syndromes, or high penetrance variants in genes associated with hereditary breast cancer.

Polygenic Risk Score

1.48

Patient's Polygenic Risk Score

The Polygenic Risk Score (PRS) is the genetic contribution to risk. It is a relative risk calculated as the multiplicative product of the patient's risk alleles weighted according to ethnicity-specific allele frequencies and odds ratios. This graph represents the breast cancer PRS range in the general population. The arrow represents where the patient falls compared to the general population. Note that PRS alone is not clinically actionable – it is just one of the factors integrated into the patient's breast cancer risk scores. Please refer to the 5 year and Lifetime for the absolute breast cancer risk scores.

Source: GTG.

² BI-RADS (Breast Imaging-Reporting and Data System) is a risk assessment and quality assurance tool developed by American College of Radiology that provides a widely accepted lexicon and reporting schema for imaging of the breast. It applies to mammography, ultrasound, and MRI.

Scientific validation: clinical evidence for accuracy of geneType for breast cancer

Accuracy of risk assessment models can be assessed in several ways. The most common is discrimination, a measure of how well the model can separate those who do and do not have a disease. The AUC (area under the ROC curve), or c-statistic, measures test discrimination – that is, the probability that a predicted risk is higher for a case than for a non-case. The results generally range from a value of 0.5 up to 1.0 for a test with perfect discrimination.

GTG determined and validated the accuracy and clinical validity of the risk scores using approximately 800 cases and 2,000 controls from the Australian Breast Cancer Family Registry and the Australian Twins and Sisters Study. Accuracy was also cross validated in a study population independent from that used to build the risk model, the Nurses’ Health Study, a prospective cohort study of 121,700 registered nurses launched in 1976. As such, a direct benchmark comparison with gold standard breast cancer risk assessment model IBIS (Tyrer-Cuzick Model) showed favourable discriminatory performance. Notably, this was an approximate 25% improvement in test performance over the BREVAGen^{plus} test.

Exhibit 7: Direct benchmark comparison with IBIS (note: breast cancer SNP-based is the unadjusted Polygenic Risk Score)

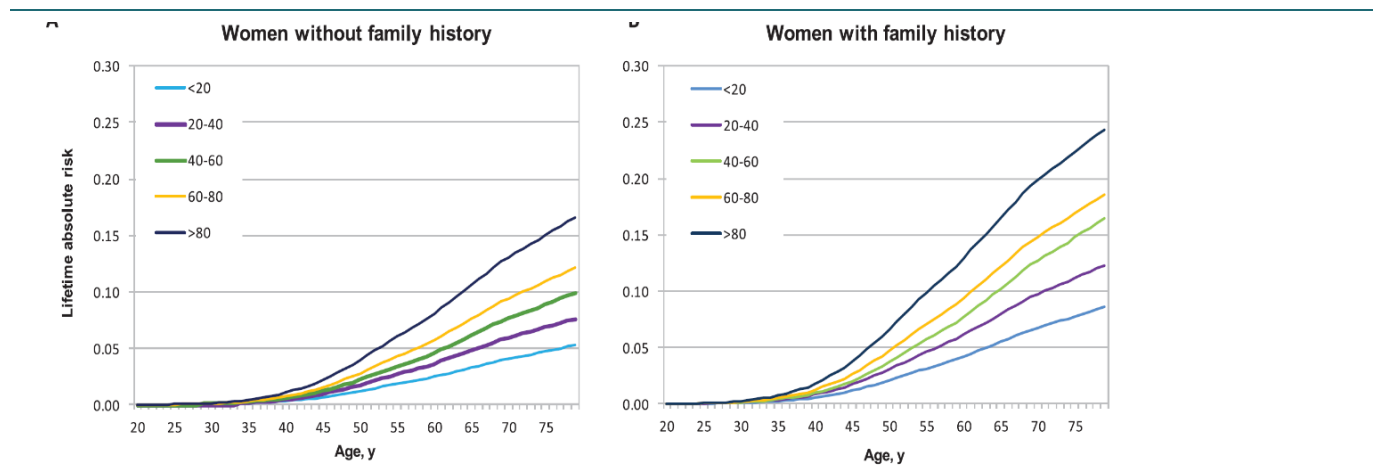
Log-Transformed Risk Score	AUC	95% confidence interval
<i>Caucasian (n = 2,601 from the Nurses Health Study)</i>		
Breast Cancer SNP-based	0.61	(0.59, 0.63)
IBIS	0.58	(0.56, 0.60)
IBIS plus SNPS	0.64	(0.62, 0.66)
geneType for Breast Cancer	0.65	(0.63, 0.67)

Source: GTG.

Clinical utility: combining PRS for breast cancer can aid in risk-stratified screening and prevention

Independent studies of breast cancer risk stratification in women of European ancestry using data for 77 common genetic variants (SNPs) validates the clinical utility of geneType’s product design. These studies showed that the PRS stratifies breast cancer risk in women with and without family history and refines genetic risk in women with a family history of breast cancer.

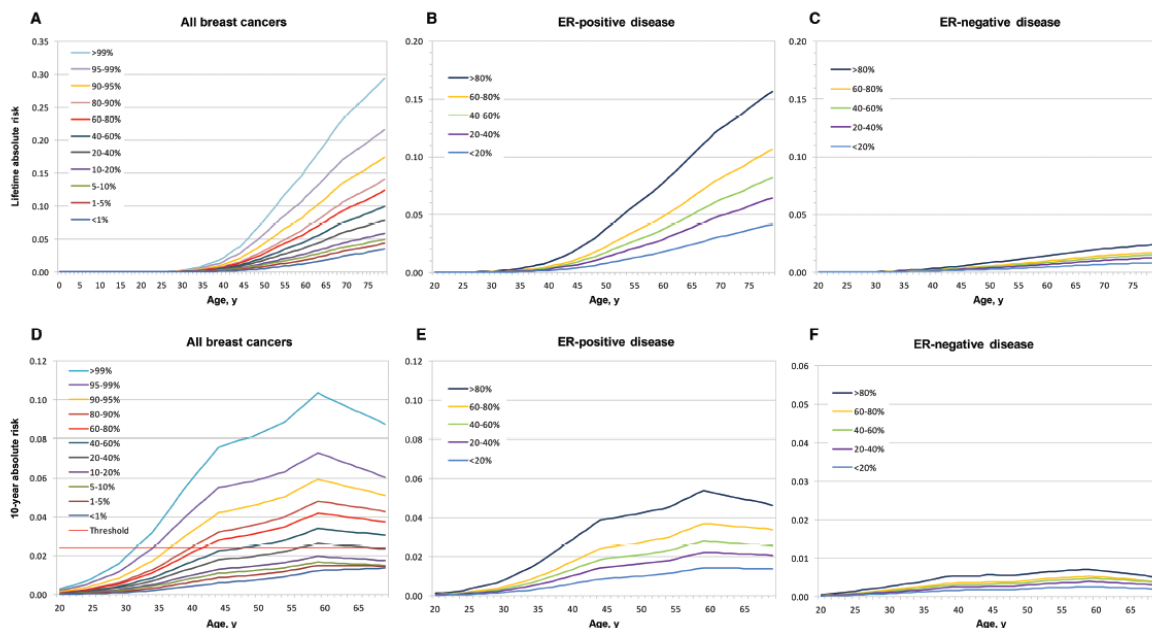
Exhibit 8: Polygenic Risk Score allows stratification of risk of breast cancer in women with and without family history



Source: Prediction of Breast Cancer Risk Based on Profiling with Common Genetic Variants; Mavaddat (2015).

Further, these studies showed that using 77 SNPs as incorporated into last iteration geneType enables prediction of subtypes of specific breast cancer, such as estrogen receptor (ER) positive, which could also be informative for prevention.

Exhibit 9: 77 SNPs can predict subtypes of breast cancer



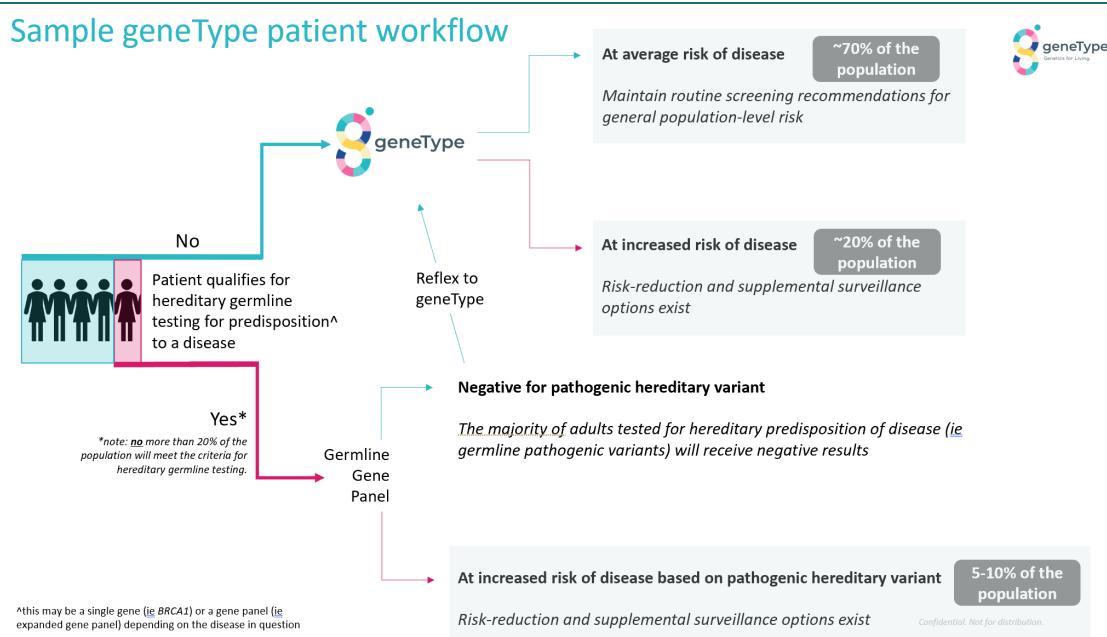
Source: Prediction of Breast Cancer Risk Based on Profiling with Common Genetic Variants; Mavaddat (2015).

Risk stratification using an absolute comprehensive score is analogous to the NCCN Guidelines for Breast Cancer Screening and Diagnosis (see Appendix 4), which gives absolute percentages (e.g., residual lifetime risk $\geq 20\%$; 5-year risk $\geq 1.7\%$). The absolute comprehensive score can be compared **directly** to these numbers. Conversely, other genetic tests results often convey risk in relative terms (e.g., ‘twice the likelihood vs. the general population’ or ‘less likely than others their age’).

In practice: how geneType fits into clinical settings

GTG is targeting primary care physicians in the first instance. Exhibit 10 shows how geneType could be incorporated in general practice.

Exhibit 10: Sample patient workflow incorporating geneType in general clinical practice



Source: GTG.

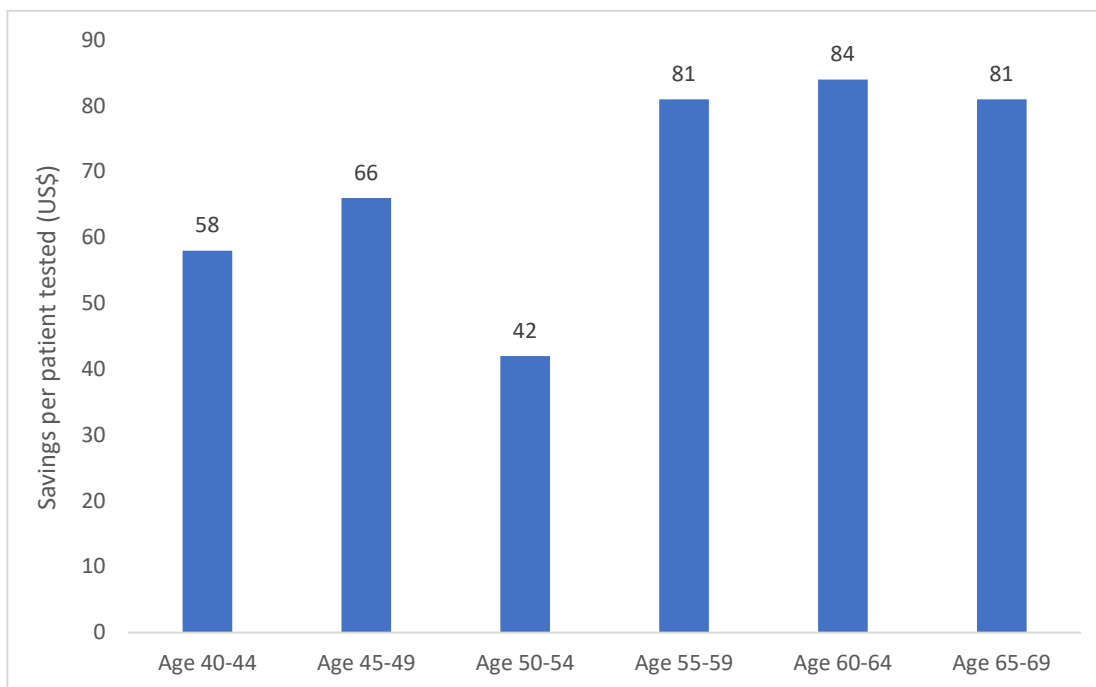
Health economics: multiple benefits, positive for reimbursement potential in the US

Reimbursement will be a key determinant of adoption and ultimate commercial success for GTG's medical B2B business in the US market. This will be determined by the ultimate cost of tests and demonstration of the health economics benefits to payers and insurers.

In June 2022, GTG announced the completion of an independently developed and validated customisable Budget Impact Model (BIM), which demonstrates significant health and economic benefits that could be directly attributed to the implementation of the geneType Breast Cancer Risk Assessment Test. These include:

- the potential to realise 3.6% annual savings in US payer costs for breast cancer treatment, equating to around US\$1.4 bn annually
- significant savings of US\$73 per patient per year equating to breakeven for the payer after 2.4 years
- an overall increase in women being health screened, from 69% to 74%
- early-stage cancer detection (I-IIA) to increase from 57% to 67%
- interval cancers (cancers that are diagnosed in between routine screening episodes) to drop from 14.8% to 8.8%.

Exhibit 11: Annual payor net savings per patient tested (US\$) – average saving of US\$73 per patient per year



Source: ALVA10 (excludes cost of GTG test; treatment and screening costs only).

Targeting major stakeholders in US healthcare market:

Payers, insurers, primary care physicians, specialists, surgeons, allied health practitioners

The breadth of managed care providers and drive towards cost containment in the US health care system represents a significant opportunity for new technologies demonstrating benefits relating to health economics. Notwithstanding the payers (employer groups) themselves, the US healthcare system is characterised by the key role of health insurers. These intermediaries operate as 'group purchasing organisations' by negotiating with service providers (i.e., health care professionals) and, with their substantial purchasing power, reduce the cost for employers of servicing their obligations to employees. As such, commercial health insurance companies can account for large numbers of 'covered' lives. In 2017, for example, the five largest commercial health insurance companies (UnitedHealthcare, Anthem, Aetna, Cigna, and Humana) together had 125m members, or roughly 43% of the country's insured population. The potential health economics benefit of incorporating geneType bodes well for discussions now underway in the US for GTG.

Direct to Consumer (EasyDNA and AffinityDNA)

EasyDNA

In July 2021, GTG entered the direct-to-consumer genomic testing market with its acquisition of EasyDNA from private equity firm BelHealth Investment Partners for US\$4m in cash and scrip.

The acquisition provided GTG with a portfolio of genomics-based laboratory tests including paternity, oncology and health and wellbeing along with agreements with 12 laboratories in North America, Asia Pacific, and Europe. In addition, EasyDNA provided GTG with an online sales platform spanning 70 websites in 40 countries and six brand identities. In May 2022, GTG launched the rebranded EasyDNA.

AffinityDNA

In July 2022, GTG acquired the direct-to-consumer e-commerce business and distribution rights associated with AffinityDNA for £555k, adding a variety of DNA tests including lifestyle, health, and wellbeing DNA-based tests, relationship and ancestry DNA testing, as well as animal testing relating to allergies and tolerances via online marketplaces. Headquartered in Hove, UK, AffinityDNA is an industry-leading DNA testing company with more than 10 years' experience and has established partnerships with some of the most highly accredited laboratories in the world.

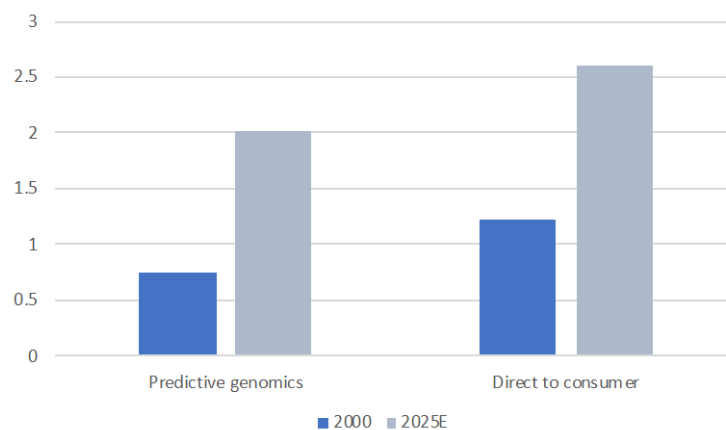
AffinityDNA generates a majority of its sales from the UK, USA and Europe. Its most popular product is genetic testing for dogs, followed closely by legal and paternity testing; together, these made up approximately 71% of overall FY21 revenue.

AffinityDNA adds incrementally to EasyDNA and strengthens GTG's direct-to-consumer channel. AffinityDNA revenue is generated from the sale of test kits to customers in the US, UK and Europe via a network of websites, including Amazon.

Market Opportunity

With its broad portfolio and expanded distribution channels, GTG is well positioned to win a share of the rapidly expanding markets of both predictive genomics and direct to consumer genetic testing. (Predictive genomics includes all tests in GTG's medical B2B and customer-initiated test divisions, while 'direct-to-consumer' includes tests marketed through GTG's direct-to-consumer division.) The predictive genomics market is currently valued at around US\$0.76b³, and is expected to reach US\$1.3b by 2025, representing a CAGR of 16.3%. Similarly, the direct-to-consumer (DTC) market is valued at US\$1.22b⁴ and is expected to reach US\$2.6b by 2025, equating to a CAGR of 18.1%.

Exhibit 12: Estimated global revenue growth in genomic testing (US\$bn)



Source: GTG (from Newswire and Technavio Market Research).

³ Newsire-Predictive Genetics Market Research Report by Type, by Demographics, by Test Type, 6 January 2022

⁴ Technavio Market Research reports -Direct-To-Consumer Genetic Testing Market by Distribution Channel, Service, and Geography - Forecast and Analysis 2021-2025

Research & Development Projects – Focusing on Clinical Utility

Although development of statistical and predictive algorithms remains an active area of research internally, GTG’s R&D focus as reflected by current collaborations is validating existing tests to strengthen the case for reimbursement.

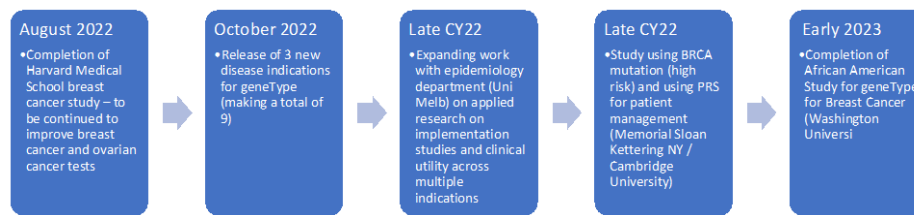
Exhibit 13: Current collaborations and partnerships

Indication	Technology	Collaborator/ Partner	Status	Notes
Breast cancer	geneType for Breast Cancer	The University of Melbourne	Ongoing - to be expanded late 2022 to cover clinical utility of multiple cancer tests	Working with epidemiology department in applied research on implementation studies and clinical utility across multiple indications
Breast cancer	geneType for Breast Cancer	Memorial Sloan Kettering New York/Cambridge University	Scheduled for completion late 2022	Study using BRCA mutation (high risk) and using polygenic risk score for patient management
Breast cancer (African American Study)	geneType for Breast Cancer	Washington University	Just commenced, to run for 6 months. Scheduled for completion early 2023	To cross validate in an African American population
Breast cancer	geneType for Breast Cancer	Harvard Medical School (Nurses Health Study)	Breast cancer study completed August 2022. To be continued to improve breast cancer and ovarian cancer tests	Validate ovarian cancer and improve performance of breast and ovarian cancer test (expected by mid CY23)

Source: GTG.

Exhibit 14 shows a timeline of new R&D projects and their anticipated release dates.

Exhibit 14: Development timeline

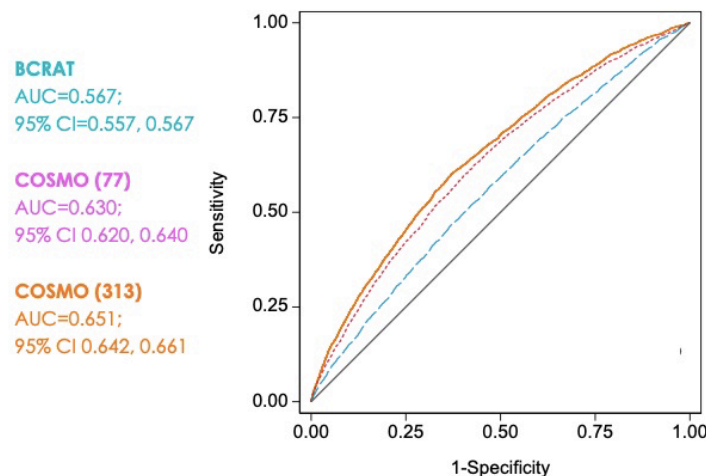


Source: GTG.

The next-generation iteration of geneType for breast cancer contains 313 SNPs, recently upgraded from 77 SNPs. This improves the test’s discrimination and calibration, the two underlying performance metrics by which the ‘accuracy’ of risk assessment tests are judged. The end result is better risk stratification for patients.

Exhibit 15 shows the meaningful improvement to the geneType for breast cancer offering that will occur when the new SNPs are integrated into this test.

Exhibit 15: Superior performance for geneType for breast cancer with 313 SNPs vs 77 SNPs and BCRAT (Gail model, a widely used model considered a ‘gold standard’, which is based on traditional clinical risk factors)



Source: GTG.

Commercial Strategy – Broad-Based Portfolio Drives Three-Pillar Strategy

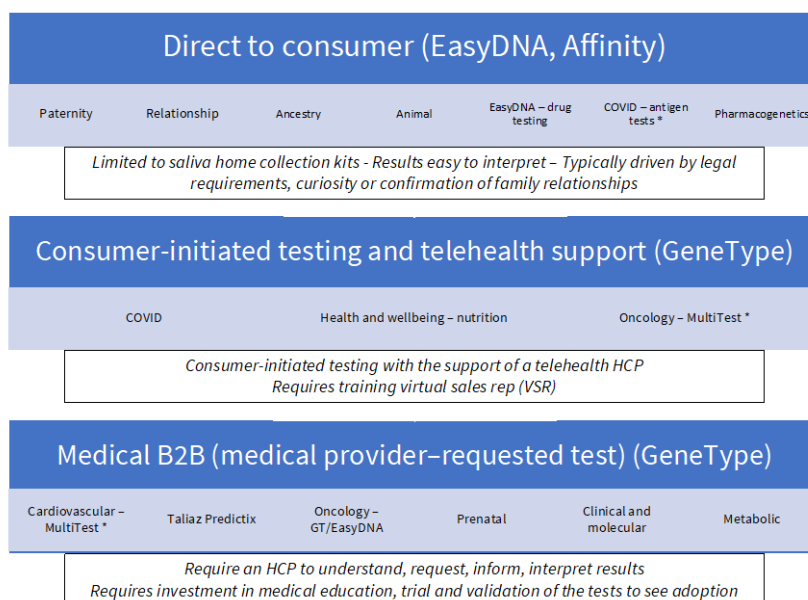
Multiple Pathways to Market

GTG's commercial strategy has been recalibrated over the past 12 months to better align with its divisional structure, expanded portfolio of tests and global push. The multi-brand strategy is designed to leverage an expanded portfolio of tests, comprising 50 tests across 14 categories, new channels, and entry into consumer segments through integration of EasyDNA and AffinityDNA, and commercial launch of the geneType Multi-Risk Test.

GTG's strategy comprises three elements or 'pillars' reflecting three distinct market segments in genomic testing.

- direct-to-consumer – targeting consumers
- consumer-initiated testing – targeting self-directed consumers to drive demand of medical tests requiring GP input
- medical business to business (B2B) – targeting specialists, GPs, allied health and insurers and payers.

Exhibit 16: GTG's three-pillar strategy with its associated brands and test availability



Source: GTG. *Available upon regulatory approval.

Strategic Initiatives Underway on All Fronts

Medical business to business (B2B)

United States: GTG is targeting the three key sales channels: (1) independent doctor networks, (2) concierge medicine, and (3) payer systems. The finalisation of the ALVA10 budget impact model (BIM) that was commissioned by GTG, which details the health economics benefits of geneType for breast cancer, should support discussions with national payers now underway. The company is also raising awareness amongst healthcare professions by presenting geneType technology at major KOL meetings such as the San Antonio Breast Cancer Symposium in 2021.

ALVA10 has been engaged with an ongoing retainer as a dedicated market access team to secure payer coverage and reimbursement. ALVA10's independently developed and validated BIM illustrates the clinical pathways patients would experience and the economic implications of commercialising and using a test or device. The BIM's main finding is the potential for US payers to reduce the annual costs of breast cancer treatment by 3.6% or US\$1.4 bn by using geneType.

US payers, including commercial insurers, large employers, and benefit groups (eg Medicare) are typically reluctant to cover new diagnostic tools, and reimbursement can take years to receive. GTG's customisable BIM (1) helps US payers better quantify the economic impact of geneType for breast cancer prior to commercialisation – minimising their technology adoption risk, and (2) will enable geneType to identify the US payers who will most likely be fast adopters.

Australia: GTG is partnering with leading obstetrics and gynecology specialist, Associate Professor Charles Siles, founder of Melbourne-based Siles Health. Siles Health operates nine clinics across Victoria which specialise in obstetrics and gynaecology, delivering a comprehensive range of personalised healthcare from screening to treatment for women.

The partnership provides immediate access to Siles Health’s 1,000-strong current active referral network of primary care physicians and 15,000 patients annually. Siles Health will provide a dedicated in-house genetic counselling service for high-risk patients, creating actionable patient pathways, as well as dedicated genetic counselling support to referring physicians.

Separately, the company is providing geneType for breast cancer risk to Prof Bruce Mann at Royal Women’s Hospital in Melbourne and in the process of introducing geneType for breast cancer risk to 40 medical practices in the geneType Hub concept, supported by marketing partner, Hahn Health.

Europe: The subsequent launch of Carrier Testing and Non-Invasive Prenatal Tests (NIPT) into Europe following the acquisition of EasyDNA in 2021 lays the foundation for introducing geneType through that channel.

Consumer-initiated testing

United States: The company is raising awareness of its consumer-initiated testing product among healthcare professionals through a marketing campaign targeting healthcare practitioners (see Exhibit 17).

Australia: GTG is raising consumer awareness working with allied healthcare market platforms and special interest groups (eg, AusDoc and Breast Cancer Foundation). It is also executing a multi-channel digital engagement program targeting GPs.

Direct to consumer

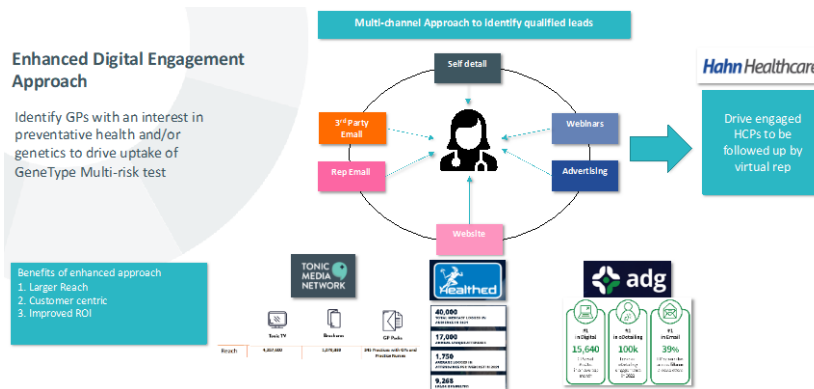
Activities include the completed launch of the DNA storage solution in the Melbourne laboratory and partnering initiatives in India with stud farms extending paternity testing into the equine industry.

Exhibit 17: Marketing plan overview by segment

OBJECTIVE	Build further awareness and credibility for GeneType parent brand and company	Build awareness and trust in current market-ready tests	Prepare markets and stakeholders to positively receive future test launches
Direct to Stakeholder	✓	✓	✓
PR Campaign Activations	✓	✓	✓
Product Campaigns			✓ (US only)
Search & Google Ads	✓	✓ (Targeting HCPs only in AU)	✓ (Targeting HCPs only in AU)
Website Blog Content	✓	✓	✓
Always-On Social (Organic & Paid)	✓	✓ (US only)	✓ (US only)
Database Growth		✓	✓

Source: GTG.

Exhibit 18: Sample marketing strategy overview – engagement plan for medical B2B in Australia



Source: GTG.

Competitive Landscape

There have been no direct competitors actively marketing a similar product array in the sporadic breast cancer risk assessment space until recently. With increased public awareness and acceptance of personalised medicine and cancer genomics, it is anticipated that more predictive genetic testing products aimed at identifying cancer risk will be developed to directly compete with GTG's offerings.

Main Competitors in Polygenic Risk Score (PRS) Space

Competition is increasing incrementally in the PRS space, although there are no direct competitors in the breast cancer segment as yet. **Myriad** has a PRS + clinical risk (IBIS model) test for their patients who reflex negative from HBOC testing. While the company has stated that it will open up tests to the general population, at this point, it still only offers testing to those who qualify clinically for hereditary testing. **Ambry** also has a breast cancer PRS + clinical risk test, but only for negative reflex HBOC (hereditary breast and ovarian cancer). This has been taken off the market and back to a R&D pilot setting. **Allelica** offers PRS testing but does not integrate clinical risks into its algorithms except for its cardiovascular disease test.

Other Competitors

Genomics PLC	Announced in March 2019 that it was developing PRS tests for several diseases including breast cancer. Genomics PLC is a UK-based biotech spin-out company from the University of Oxford, founded in 2014. Like GTG, their test calculates a PRS from the individual's genetic information, which is then integrated with non-genetic information to generate actionable insights targeted to the individual's risk profile, based on clinical guidelines and the latest scientific findings.
Myriad Genetic Laboratories (NASDAQ: MYGN)	Breast cancer risk-prediction tool, riskScore® (first announced in 2017), predicts the 5-year and remaining lifetime risk for breast cancer. Founded in 1991, the US-based company has over 25 years of experience in variant classification and reclassification of BRCA1/2. Its MyRisk™ Hereditary Cancer Test with riskScore® incorporates the patient's individual clinical risk factors, family history, and unique genetic, ancestry-informed breast cancer risk markers. riskScore® analyses over 100 genetic markers combined with the Tyler-Cuzick model and is calculated for women aged 18–84, but only if they test negative on MyRisk™ for breast cancer related gene mutations and have no personal history of breast cancer, LCIS, hyperplasia, atypical hyperplasia or breast biopsy with known results.
Ambry Genetics Corporation	Sells a precision risk tool that provides lifetime breast cancer risk information alongside comprehensive cancer risk testing for heart, neurological and rare conditions. Founded in 1999, this US-based company boasts the largest genetic sequencing lab in the world, acquired by Konica Minolta in 2017.
Other competitors	<p>Counsyl Inc (US) (new early-stage entrant); Invitae Corporation (US) (new early-stage entrant)</p> <p>23andMe and Intergenetics have recently developed SNP-based risk tests that, whilst not currently direct competitors to GTG's products, are attracting significant consumer interest. However, these companies, alongside several others including deCODE (Iceland), have unsuccessfully commercialised SNP-based genetic tests to both physicians and consumers in the sporadic breast cancer risk assessment space, either due to inadequate and compelling scientific validation and/or insufficient commercial impetus and capability.</p> <p>Academic centres and affiliated research and development bodies in the US and Europe are reportedly exploring the validity and clinical viability of SNP-based commercial tests in clinical settings.</p> <p>Many of these larger potential competitors have established name and brand recognition and more extensive collaborative relationships, but it is unclear to what extent these entities represent a real competitive risk to GTG in the near or long term.</p>

Intellectual Property

The Genetype AG acquisition in 1999 enabled the company to attain ownership rights to a potentially significant portfolio of issued patents, which has since expanded both organically and through third-party purchases of intellectual property assets.

In February 2022, the company was granted a patent called ‘Methods of Assessing Risk to Developing a Severe Response to Coronavirus Infection’. This patent covers the proprietary technology incorporated into GTG’s geneType COVID-19 Risk Test. The test provides a risk score that can be used to estimate the probability of an individual developing severe symptoms requiring hospitalisation, should they become infected with COVID-19.

In June 2021, the company was granted a patent called ‘Computer Systems and Methods for Genomic Analysis’, which covers efficient methods for identifying variants that occur in the human genome and relating those variants to the genetic basis of disease and drug response. These methods form the basis of GWASSs, particularly those focused on identifying SNPs associated with drug response.

In June 2020, GTG received approval for its patent called ‘Methods for Assessing Risk of Developing Breast Cancer.’ This patent covers the company’s proprietary panels of SNPs and the combination of clinical and phenotypic risk models to create the geneType for breast cancer tool.

Exhibit 19: Patent portfolio (as at September 2022)

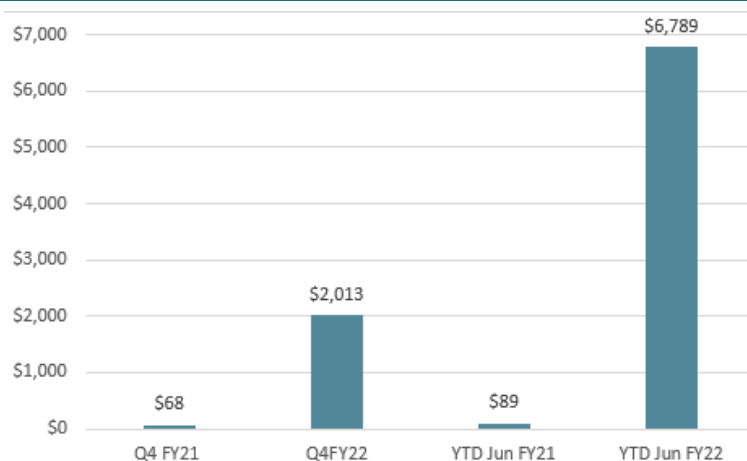
Number	Title	Inventors	Applicant	Filing date	Status
Provisional Applications					
2021903955	Breast cancer risk assessment	Allman R, Dite GS	Genetic Technologies Limited	7-Dec-21	Provisional Pending
2022901108	Methods of assessing risk of developing prostate cancer	Allman R, Dite GS	Genetic Technologies Limited	27-Apr-22	Provisional Pending
2022901988	Methods of assessing risk of developing ovarian cancer	Allman R, Dite GS	Genetic Technologies Limited	15-Jul-22	Provisional Pending
PCT Applications					
US 11,257,569	Methods of assessing risk of developing a severe response to Coronavirus infection	Dite GS, Murphy NM, Allman R	Genetic Technologies Limited	27-May-20	Granted
17/667,282	Methods of assessing risk of developing a severe response to Coronavirus infection	Dite GS, Murphy NM, Allman R	Genetic Technologies Limited	27-May-20	PCT Pending
PCT/AU2021/050507	Methods of assessing risk of developing a severe response to Coronavirus infection	Dite GS, Murphy NM, Allman R	Genetic Technologies Limited	27-May-20	PCT Pending
AU 2020903793	Methods of assessing risk of developing a disease	Wong K, Murphy N, Dite G, Gafni A, Allman R	Genetic Technologies Limited	20-Oct-20	PCT Pending
National Phase Applications					
US 11,072,830	Methods for breast cancer risk assessment	Hinds D, Walser B	Genetic Technologies Limited	1-Jun-09	Granted
		<i>Also granted in Australia, Canada, China, Europe, Hong Kong, India, Israel, Japan, Mexico</i>			
US 10,683,549	Methods for assessing the risk of developing breast cancer	Allman R	Genetic Technologies Limited	30-Sep-14	Granted & Pending
		<i>Granted in Australia, China, Israel, Japan, Mexico, Singapore, South Korea; pending in Canada, Europe, Hong Kong</i>			
AU 2018213400	Improved methods for assessing risk of developing breast cancer	Allman R	Genetic Technologies Limited	24-Jan-17	Pending
AU 2017212152	Methods of assessing risk of developing breast cancer	Allman R, Dite G, Hopper J	Genetic Technologies Limited & University of Melbourne	13-Oct-18	Pending
AU 2017212152	Methods for assessing risk of developing colorectal cancer	Jenkins M, Buchanan D	University of Melbourne	28-Jan-16	Granted and Pending

Source: GTG.

Financials – Transformational Year Establishes New Commercial Baseline

FY2022 marked a transformational year for the company with the global launch of the geneType brand, the acquisition of EasyDNA (executed in August 2021) and the acquisition of AffinityDNA (executed in July 2022), effectively moving GTG onto a firm commercial footing and baseline. Exhibit 20 highlights the uplift in cash receipts following the contribution of EasyDNA sales of direct-to-consumer genomic tests following the acquisition of the EasyDNA business.

Exhibit 20: Cash receipts (Appendix 4C), A\$000's



Source: GTG.

Final FY22 detailed financials showed consolidated revenues, excluding other income, of A\$6,794,816, an increase of 5536% on the previous corresponding period, compared with A\$120,554 in the previous year. This resulted in a gross profit of A\$3,781,282 compared with a gross loss of A\$50,000 in the prior year. Increases in operating expenses were consistent with the company's focus shift from R&D to commercialisation with a step-up in employee benefits expenses, up 52% year on year, and advertising/promotional expenses, up 332% year on year. The company ended FY22 with A\$11,731,325 in cash on the balance sheet and nil debt.

Exhibit 21: FY22 profit and loss statement, A\$000's

A\$000's	FY21A	FY22A	% vs PCP
Revenue	121	6,795	5536%
Raw materials	(185)	(2,692)	1356%
Changes in inventories	14	(321)	n/a
Gross profit	(50)	3,781	n/a
Other income	1,560	2,783	78%
Commissions		157	n/a
Employee benefits expenses	3,868	5,869	52%
Advertising and promotional expenses	436	1,885	332%
Professional fees	1,461	1,835	26%
Research and development expenses	1,166	706	-39%
Impairment expenses	32	564	1660%
Other expenses	1,284	2,154	68%
Total Operating Expenditure	8,247	13,170	60%
EBITDA	(6,737)	(6,605)	-2%
D&A expenses	386	579	50%
Total EBIT	(7,124)	(7,184)	1%
Finance costs	(16)	(15)	-7%
Finance income	62	36	-42%
Profit (loss) before tax	(7,078)	(7,163)	1%
Income tax	-	32	
Net loss for the year	(7,078)	(7,131)	1%

Source: GTG.

Valuation

We value GTG at A\$118m or A\$0.012 per share (diluted), using discounted cash flow (DCF) methodology on free cash flow and based on 9,234m shares on issue and 265m options respectively. This represents potential upside to the current share price of approximately 192%. Key DCF inputs are beta of 1.25, WACC of 12.5% and terminal growth rate of 2%. We think DCF methodology allows for more granular modelling of accumulated tax losses and best captures the cash flow generation potential of the business over time. Our fair value per ASX-listed share (diluted) for GTG (GTG.ASX) equates to US\$5.37 per Genetic Technologies Limited Sponsored ADR listed on NASDAQ (GENE.US).

Exhibit 22: Base-case DCF valuation and key metrics

		Jun-22 2022	Jun-23 2023	Jun-24 2024	Jun-25 2025	Jun-26 2026	Jun-27 2027	Jun-28 2028	Jun-29 2029	Jun-30 2030	Jun-31 2031	Jun-31 2032
EBIT	A\$m	(7.2)	(2.0)	0.3	3.2	6.0	8.6	11.3	13.9	16.7	19.6	22.6
Tax at standard rate	A\$m	-	-	-	-	-	-	-	-	-	-	-
Post-tax EBIT	A\$m	(7.2)	(2.0)	0.3	3.2	6.0	8.6	11.3	13.9	16.7	19.6	22.6
Depreciation & Amortization	A\$m	(0.6)	(0.5)	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)
Post-tax cash flow	A\$m	(7.8)	(2.5)	0.1	3.1	5.8	8.5	11.1	13.8	16.5	19.4	22.5
Less capex	A\$m	(0.1)	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)
Less change in working capital	A\$m	0.2	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.1)	(0.1)
Free cash flow	A\$m	(7.7)	(2.7)	(0.0)	2.9	5.6	8.3	10.9	13.6	16.3	19.2	22.3
Discount coefficient	years	0.0	1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0
Discounted cash flow	A\$m		(2.4)	(0.0)	2.0	3.5	4.6	5.4	6.0	6.4	6.7	6.9
Sum of discount streams	A\$m	38.9										
Terminal growth	%	2.0%										
Future value into perpetuity	A\$m	216.6										
NPV of terminal value	A\$m	68.0										
PV of cash flows	A\$m	107.0										
PLUS: Value of investments	A\$m	-										
LESS: Net debt	A\$m	(11.1)										
Equity value	A\$m	118.0										
Ordinary shares (includes options)	m	9,499.0										
Value per share	A\$	0.012										
NASDAQ												
Value per share	A\$	7.46	600.00									
Value per share	US\$	5.37	0.72									

Source: MST Access.

Upside risks to our valuation, based on key drivers, include higher-than-expected penetration of targeted market segments both in the US and Australia, better-than-assumed pricing for both geneType and DTC products, and lower-than-expected operating expenses related to advertising and marketing costs. Downside risks to our valuation relate to the same assumptions and include higher-than-expected competition impacting GTG's adoption.

Our base-case valuation DCF valuation of A\$0.012 per share (diluted) is highly sensitive to discount rate and terminal growth rate inputs. Given the transformation in the company business model, we think it is appropriate to include a sensitivity matrix to show how our valuation estimate would change under different combinations of these two inputs.

Exhibit 23: DCF valuation sensitivity matrix (key inputs tested: discount rate and terminal growth rate)

		WACC					
	0.012	10.5%	11.5%	12.5%	13.5%	14.5%	15.5%
Terminal growth rate	0%	0.014	0.012	0.011	0.010	0.009	0.008
	1%	0.015	0.013	0.012	0.010	0.009	0.008
	2%	0.016	0.014	0.012	0.011	0.010	0.009
	3%	0.018	0.015	0.013	0.012	0.010	0.009
	4%	0.020	0.017	0.014	0.013	0.011	0.010

Source: MST Access.

Sensitivities and Risks

Competition

Although GTG's core technologies are novel, the company operates in a rapidly evolving and competitive marketplace alongside larger companies with access to greater financial resources. The ability of these larger competitors to fund development programs and commercial activities could limit GTG's ability to win market share.

Further, given the proliferation of direct-to-consumer genetic testing products, GTG may need to increase spending in marketing to support these newly acquired brands.

New Product Development

Increasing competition will require ongoing innovation to drive new product development and next-generation refinements of existing products. Although validation of laboratory-developed tests can be relatively rapid, which bodes well for this process, continuous product improvement may be unsustainable over the long term.

Further, as an LDT manufacturer with its own CLIA laboratory, capacity constraints may become a limiting factor to achieving economies of scale in a business servicing the offshore market.

Reimbursement and Commercial Potential – Achieving and Maintaining

Reimbursement will be a key determinant of adoption and ultimate commercial success for GTG's medical B2B business in the US market. This will depend on the ultimate cost of tests and demonstration of the health economic benefits to payers and insurers. Despite reimbursement studies, including the preparation of budget-impact models by GTG in breast cancer applications versus standard-of-care screening pathways, reimbursement has not been secured in the US at this point.

Regulatory

CLIA certification of Melbourne laboratory: In 2011, GTG's Melbourne-based laboratory became the first lab in Australia to be certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), allowing it to sell a portfolio of services into the US market. This certification is in addition to GTG's NATA and RCPA accreditation for Asia Pacific and ISO for European markets. As such, any changes to certification status could negatively impact its products' commercial potential.

FDA oversight of LDT products: Further, given the CLIA certification, GTG can validate new tests at its own laboratory, reducing time to market and driving innovation. This is also supported by the fact that laboratory-developed tests (LDTs) do not typically require premarket review for marketing. However, the COVID-19 pandemic fuelled rapid development of LDTs to help increase COVID-19 testing capacity and led to increased scrutiny of LDTs by the US Food and Drug Administration (FDA). As such, GTG remains vulnerable to changes in FDA regulation of LDTs.

Direct-to-Consumer–Related Issues: Product Liability Given Third-Party Contracted Labs

GTG's entry into the direct-to-consumer markets, through its acquisition of EasyDNA and AffinityDNA, expanded its portfolio and created economies of scale. However, this move also increased GTG's exposure to product liability risk given the reliance on third-party laboratories for supply of tests. This would include, by extension, third-party data interpretation. As such, we would see a transition of all EasyDNA and AffinityDNA production to GTG's facility as mitigating this risk.

Intellectual Property

The success of GTG's programs will depend on its ability to defend intellectual property (IP) assets surrounding its technologies. Despite a solid patent position, including 25 patents around geneType or related products, maintaining and defending potential infringements can be costly.

Cybersecurity and Data Privacy

Given the sensitive nature of genomic testing data and the reliance on online platforms for collection and transmission of personal information, GTG could be vulnerable to breaches of cybersecurity and loss or corruption of data.

Board and Management

Board of Directors

Mr Peter Rubinstein – Non-Executive Director and Chairman. Mr Rubinstein joined the Board as a director in 2018 and was appointed as chairman in April 2020. He is also a lawyer and has over 20 years of experience in early-stage technology commercialisation through to public listings on the Australian Stock Exchange, with exposure to the creation, launch, and management of a diverse range of technology companies in the biotech, digital payments, and renewable energy sectors. Mr Rubinstein is also a Non-Executive Director of DigitalX Limited (ASX: DCC).

Dr Lindsay Wakefield – Non-Executive Director. Dr Wakefield was appointed to the Board in September 2014. Dr Wakefield has been a biotech investor for more than 20 years and is also the CEO of Safetech, an Australian manufacturer and supplier of dock equipment, freight hoists and custom lifting solutions.

Mr Nick Burrows – Non-Executive Director. Mr Burrows was appointed to the Board in September 2019. He has over 30 years of commercial experience, underpinned by his background as a chartered accountant and registered company auditor. Mr Burrows is a contemporary independent Non-Executive Director across the listed, government and private sectors and brings expertise in corporate governance as well as strategic, commercial, financial and risk management oversight.

Dr Jerzy ‘George’ Muchnicki – Non-Executive Director & Medical Advisor. Dr Muchnicki was appointed to the Board in January 2018 and was Interim Chief Executive Officer from September 2019 until the appointment of Mr Simon Morriss to the role. He has over 14 years of experience in commercialisation and R&D funding of companies within the biotechnology sector from gene silencing to regenerative medicine.

Senior Management Team

Mr Simon Morriss – Chief Executive Officer. Mr Morriss was appointed CEO in February 2021 and has over 20 years of experience within the pharmaceutical, healthcare and FMCG industries. Prior to GTG, he held senior executive positions at Sanofi and Blackmores, bringing significant experience in team management and execution across sales, marketing and brand building. He will lead GTG’s commercialisation strategy and continue to drive innovation across the business.

Mr Mike Tonroe – Chief Financial Officer. Mr Tonroe joined GTG in June 2021 with over 25 years of experience in overseeing the finance function at both management and board-level positions for private and listed companies in Australia, the UK, US and Canada. Prior to GTG, Mr Tonroe was CFO and Company Secretary at Opthea and the Australian Synchrotron in Melbourne, in addition to working for Deloitte and KPMG in the UK and Hong Kong. He is also a fellow of the Institute of Chartered Accountants in England and Wales, and a member of the Australian Institute of Company Directors.

Dr Richard Allman – Chief Scientific Officer. Dr Allman joined GTG in 2004 and was appointed as Scientific Director in December 2012. He has over 20 years of scientific and research experience in the UK academic arena and Australian commercial sector, bringing experience in research leadership, innovation management, and intellectual property strategy, covering oncology, diagnostics, and product development. Prior to entering the biotechnology sector, Dr Allman’s academic career encompassed oncology research, drug development, and assay design.

Dr Erika Spaeth - Director of Clinical Affairs & Medical Education. Dr Spaeth joined GTG in 2016, with broad experience in the high-complexity lab space, from assay development to regulatory oversight of laboratory developed tests in oncology. She is responsible for the development of clinical content and clinical rationale for GTG products, including development and execution of commercial clinical research, pilot studies and management of academic research collaborations. Dr Spaeth completed her postdoctoral training at the MD Anderson Cancer Centre, holds a PHD in Biomedical Sciences from the University of Texas Health Science Center and a B.S. in Molecular Biology from the University of Connecticut.

Mr Carl Stubbings – Chief Commercial Officer. Mr Stubbings joined GTG in September 2021 and is an experienced senior executive in the biotechnology and diagnostics industry. Prior to GTG, he served as Senior Vice President for Panbio USA (1995–2005), Vice President of Sales and Marketing for Focus Diagnostics (2008–2012), Chief Business Officer of Benitec Biopharma (2012–2016), CEO and MD at Sienna Cancer Diagnostics (2019) and COO at BARD1 Life Sciences (now INOVIQ).

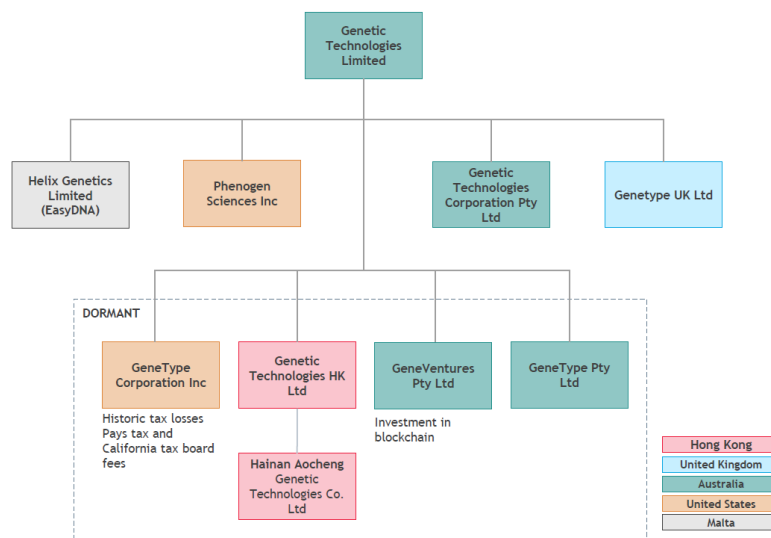
Appendix 1 – Shareholder Registry and Corporate Structure

Exhibit 24: Top 20 shareholders (as at 31 July 2022)

Ordinary Shareholders	No. Shares	Percentage
BNY MELLON ASSET MANAGEMENT	6,419,545,711	69.52%
PETER RUBINSTEIN	308,132,009	3.34%
JERZY MUCHNICKI	263,085,885	2.85%
DOMA 193 PTY LTD	144,551,379	1.57%
BIOA TRUST	75,849,310	0.82%
MONUMENT HILL PTY LTD	42,000,001	0.45%
SUSAN SPITERI	41,142,778	0.45%
HILCOR TRADING PTY LTD	40,000,000	0.43%
WARWICK WRIGHT	33,000,000	0.36%
JOHN CHRISTOPOLOUS	26,000,000	0.28%
BILL GIANOULAS	25,000,000	0.27%
AQUASAFE INVESTMENTS PTY LTD	24,248,154	0.26%
SAYCA PTY LTD	22,500,000	0.24%
CAN ODABAS	20,000,000	0.22%
AP 300 PTY LTD	18,750,000	0.20%
BLR CRANES PTY LTD	18,397,239	0.20%
DANCHU PTY LTD	16,400,000	0.18%
BFG FARMS PTY LTD	15,000,000	0.16%
JACK GURMAN	15,000,000	0.16%
DAVID ROSEMAN	14,250,036	0.15%
Top 20 Total	7,582,852,502	82.12%

Source: IRESS, GTG.

Exhibit 25: Genetic Technologies' subsidiaries



Source: GTG.

Appendix 2 – Company History

Founded in 1989, Genetic Technologies listed its ordinary shares on the ASX in 2000 and its ADRs on the NASDAQ in 2005.

Exhibit 26: Company history

2003	<p>Strategic alliance with Myriad Genetics Inc. provides exclusive rights to perform DNA testing for susceptibility to a range of cancers in Australia/NZ</p> <p>Establishes cancer susceptibility testing facility (which is then NATA-accredited) within its Australian laboratory</p> <p>Joins GENDIA as the sole reference laboratory for the network in Australia/NZ – allows GTG to offer comprehensive testing services to its Asia-Pacific customer base and increase exposure to other markets</p>
2007	<p>Identifies several SNPs, each with an associated small relative risk of breast cancer, leading to development of BREVAGen™</p>
2009	<p>Pivots to creating a portfolio of tests aimed at providing cancer management assistance to medical clinicians in Asia Pacific, with the tests being created both in-house and in-licenced from third parties</p>
2010	<p>Purchases assets from Perlegen Science, including BREVAGen™ breast cancer test and a suite of patents valid until 2022</p> <p>Incorporates US subsidiary to facilitate marketing and distribution of BREVAGen™ in the United States</p>
2014	<p>Releases next-generation BREVAGen<i>plus</i>, incorporating a 10-fold expanded panel of SNPs associated with sporadic breast cancer. Pivots sales and marketing efforts towards large comprehensive breast treatment and imaging centres, which are more complex entities with a longer sales cycle, but higher potential.</p> <p>Sells Heritage Australian Genetics business to Specialist Diagnostic Services Ltd (SDS)</p>
2016	<p>Executes exclusive worldwide licence agreement with University of Melbourne to develop and commercialise a novel colorectal cancer (CRC) risk assessment test</p>
2017	<p>Executes investigator-initiated Research Agreement with Ohio State University, reflecting increased industry awareness of GTG's expertise in SNP-based risk assessment</p>
2018	<p>Executes further collaborative research and services agreements with University of Melbourne; research designed to enable women with extended family history of breast cancer to use BREVAGen<i>plus</i> and increase the range of factors analysed</p>
2019	<p>Develops geneType for Colorectal Cancer and geneType for breast cancer, which was substantially improved from the legacy BREVAGen<i>plus</i> test</p> <p>Signs three-year collaboration agreement with Translational Genomics Research Institute</p>
2020	<p>Receives US Patent 'Methods for assessing risk of developing breast cancer'</p> <p>Becomes the first company in the world to successfully commercialise a polygenic risk test for breast cancer</p>
2021	<p>African American Breast Cancer Research Collaboration with Professor Colditz at Washington State University</p> <p>New Multi-Test technical validation complete and submitted to NATA and CMS for final regulatory approval</p>
2022	<p>Launches geneType Multi-Risk Test incorporating both polygenic risk and clinical risk factors</p>

Source: IRESS, GTG.

Appendix 3 – Glossary and Genomic Testing Descriptions

Exhibit 27: Glossary

Term	Details
1000 Genomes Project	An international research consortium that was set up in 2007 with the aim of sequencing the genomes of at least 1,000 volunteers from multiple populations worldwide in order to improve understanding of the genetic contribution to human health and disease
Clinical Laboratory Improvement Amendments (CLIA)	Regulates laboratory testing; requires clinical laboratories to be certified by the Center for Medicare and Medicaid Services (CMS) before they can accept human samples for diagnostic testing
Common complex diseases (CCP)	A complex disease is caused by the interaction of multiple genes and environmental factors. Complex diseases are also called multifactorial. Examples of common complex diseases include cancer and heart disease
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
Genetic	Pertaining to a gene
Genome	All of the genetic material in an organism; made of DNA (or RNA in some viruses) and includes genes and other elements that control the activity of those genes. A person's complete set of genetic material, including all of their genes
Genomics	Pertaining to the function of genetics, from structure to relationship between genetic events
Genotype	The genetic makeup of an organism
Genotyping	Determines differences in genetic complement by comparing a DNA sequence to that of another sample or a reference sequence. It identifies small variations in genetic sequence within populations, such as single-nucleotide polymorphisms (SNPs)
Genome-wide association studies (GWAS)	Large population-level studies which enable scientists to identify genes and genetic markers involved in human disease. This method searches the genome for SNPs that occur more frequently in people with a particular disease than in people without the disease. Each study can look at hundreds or many thousands of SNPs at the same time. Researchers use data from this type of study to pinpoint genetic variations that may contribute to a person's risk of developing a certain disease
Germline	The sex cells (eggs and sperm) that sexually reproducing organisms use to pass on their genomes from one generation to the next (parents to offspring) are called germ cells. This is in contrast to the other cells of the body, which are called somatic cells
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.
Health care professionals (HCP)	Physician, GP, or specialist authorised to receive patient results
The Human Genome Project	An international research project that sequenced all of the genes found in humans. This project began in 1990 and concluded in 2003. One goal of the project was to accurately sequence the 3 billion nucleotide base pairs in the human genome

Source: MST Access, various sources.

Exhibit 27 (continued): Glossary

Laboratory developed tests (LDT)	A type of in-vitro diagnostic test that is designed, manufactured and used within a single laboratory
Monogenic disorders	Single-gene disorders (e.g., BRCA1)
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)	Also known as high throughput sequencing; a 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
Phenotype	Observable characteristics or traits of an organism that are produced by the interaction of the genotype and the environment
Polygenic	Influenced by the combined effects of many genes
Polygenic risk score	A number associated with one's disease risk based on the aggregated effects of individual risk variants through a multiplicative algorithm
Single nucleotide polymorphism (SNP, pronounced 'snip')	The most common type of genetic variation among people. Each SNP represents a difference in a single DNA building block, called a nucleotide. For example, a SNP may replace the nucleotide cytosine (C) with the nucleotide thymine (T) in a certain stretch of DNA
Serious disease risk (SDR)	Risk associated with acquiring COVID-19 and requiring hospitalisation with its associated morbidities and mortalities

Source: MST Access, various sources.

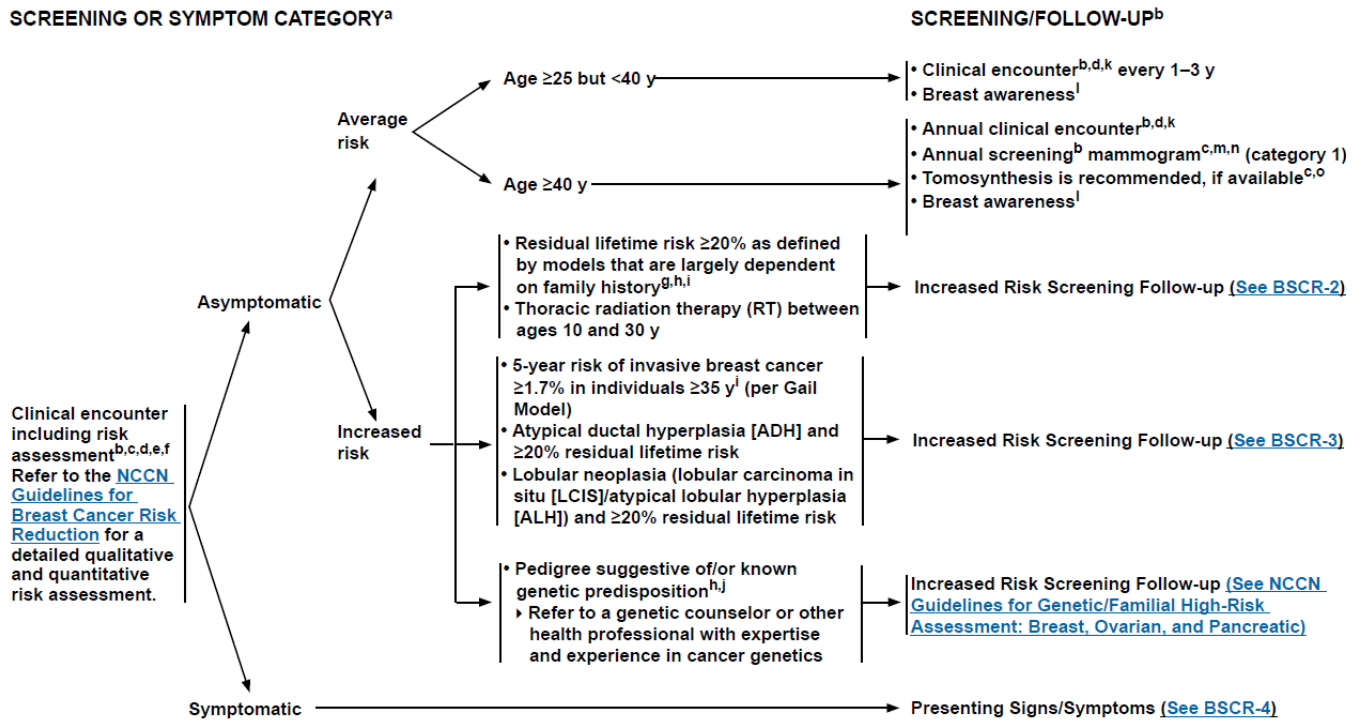
Exhibit 28: Types of genomic tests

Single gene testing	Single gene tests, which look for changes in only one gene, are done when your doctor believes you or your child have symptoms of a specific condition or syndrome. Some examples of this are Duchene muscular dystrophy or sickle cell disease. Single gene testing is also used when there is a known genetic mutation in a family.
Panel testing	A panel genetic test looks for changes in many genes in one test. Genetic testing panels are usually grouped in categories based on different kinds of medical concerns. Some examples of genetic panel tests are low muscle tone, short stature, or epilepsy. Panel genetic tests can also be grouped into genes that are all associated with a higher risk of developing certain kinds of cancer, such as breast or colorectal (colon) cancer.
Large-scale genetic or genomic testing	There are two different kinds of large-scale genetic tests: -- Exome sequencing looks at all the genes in the DNA (whole exome) or just the genes that are related to medical conditions (clinical exome). -- Genome sequencing is the largest genetic test and looks at all of a person's DNA, not just the genes. Exome and genome sequencing are ordered by doctors for people with complex medical histories. Large-scale genomic testing is also used in research to learn more about the genetic causes of conditions. Large-scale genetic tests can have findings unrelated to why the test was ordered in the first place (secondary findings), such as genes associated with a predisposition to cancer or rare heart conditions, when the test was originally looking for a genetic diagnosis to explain a child's developmental disabilities.

Source: CDC.

Appendix 4 – Current Breast Screening Guidelines

Exhibit 29: Clinical breast screening guidelines (2022)



Source: NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]).

Appendix 5 – GTG Product and Partnership Overview

Exhibit 30: GTG categories, products and partners

Category	Products	Original Technology Source	Geographies	Partners/Distributors
Direct to consumer testing (DTC) with no medical supervision	Ancestry	EasyDNA	North America, Asia Pacific and Europe	Agreements with 12 laboratories in North America, Asia Pacific and Europe
	Paternity	EasyDNA		
	Health & Wellbeing	EasyDNA		
	Pharmacogenetics	EasyDNA		
	Animal	AffinityDNA		
	Drug Testing	AffinityDNA		
	Relationship	AffinityDNA		
	Covid-Antigen Tests	AffinityDNA		
	DNA Storage	AffinityDNA		
	Consumer initiated testing (CIT) available through medical practitioners only	Health & Wellbeing - Nutrition		
Oncology - Multi-Test		geneType (PRS)		
Cardiovascular MultiTest		geneType (PRS)		
Metabolic-Multi-Test		geneType (PRS)		
COVID Risk Test		geneType (PRS)		
Pharmacogenomics		EasyDNA		
Medical business to business (B2B) healthcare professional requested test		Oncology - Multi-Test	geneType (PRS)	North America, Asia Pacific and Europe
	Cardiovascular MultiTest	geneType (PRS)		
	Metabolic-Multi-Test	geneType (PRS)		
	NIPT	EasyDNA		
	Prenatal (carrier test)	EasyDNA		
	Clinical & Molecular	EasyDNA		
	Metabolic	EasyDNA		
	Taliaz Predictix	inlicensed from Taliaz (Israel)		

Source: GTG.

Appendix 6 – Scientific and Medical Advisory Board

Dr Ora K Gordon, MD – Regional Medical Director of the Center for Clinical Genetics & Genomics. Dr Gordon is a professor of genetics at the St John Cancer Institute and Clinical Professor of Medicine at UCLA Geffen School of Medicine, with a clinical practice and research focus on hereditary risk assessment and cancer prevention. She is Chair of the Commission on Cancer Integrated Network Cancer Program and the Clinical Director of the Population Health Genomics program for Providence Southern California. Additionally, Dr Gordon is the Principal Investigator for the Geno4ME: Genomic Medicine for Everyone study. She completed medical school at the University of California and is board-certified in Internal Medicine and Medicinal Genetics.

Professor Jon Emery – Herman Professor of Primary Care Cancer Research at the University of Melbourne. In addition to his role at the University of Melbourne, Professor Emery is Director of PC4, the national primary care cancer trials group, the Primary Care Research and Education Lead for the Victorian Comprehensive Cancer Centre, and an NHMRC Leadership Fellow. Furthermore, he is a Visiting Research Fellow at the University of Cambridge and a Visiting Professor at the National University of Singapore. Professor Emery studied medicine at Cambridge and Oxford and obtained his DPhil at Oxford on computerised risk assessment for breast cancer. He has experience in leading a program of research on the role of primary care in cancer prevention, early detection and survivorship, including trials of genomic tests in primary care.

Professor Finlay Macrae AO – Head of Colorectal Medicine and Genetics, The Royal Melbourne Hospital. In addition to his role at the Royal Melbourne Hospital, Professor Finlay Macrae AO is the Principal Fellow and Professor at the Department of Medicine in the University of Melbourne, a lead clinician in the Familial Cancer Clinic at the Royal Melbourne Hospital, and a member of the Clinical Advisory Group to the Australian National Bowel Cancer Screening Program. He is a Councillor for the International Society of Gastrointestinal Hereditary Tumours (InSiGHT), and through his department, manages the world's central LOVD databases of DNA variation in the MMR and other genes predisposing to colorectal cancer, recently extending to ClinGen for ClinVar. He is a member of the Steering Committee of the National Institutes of Health (USA) Colon Cancer Family Registry; the Advisory Committee of the European Prospective Lynch Syndrome Database; and the International Scientific Advisory Committee of the Global Variome, now merged with HUGO. He is the International Vice-Chairman of the CAPP organisation for randomised controlled trials of aspirin chemoprevention in mismatch repair gene carriers, leading the Australian contribution to CAPP3. In 2021, he was awarded the Gastroenterological Society of Australia's Distinguished Research Prize.

Associate Professor Ronald Dick MBBS, FRACP, FCSANZ, Chairman of Cardiovascular Institute at Epworth Healthcare, an Honorary Cardiologist at the Alfred Hospital and Bendigo Healthcare Group. Completed his MBBS in 1979 and became a Fellow of the Australian College of Physicians in 1986. His interventional cardiology fellowship was from the University of Michigan Medical Centre USA.

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