ASX Market Announcement



FY23 Half-year Financial Results – Strong Revenue Growth Performance

Melbourne, Australia, 28 February 2023: Genetic Technologies Limited (ASX:GTG; NASDAQ: GENE, "Company", "GTG"), a global leader in guidance-driven genomics-based tests in health, wellness and serious diseases, is pleased to present its half-year results and operational highlights for the six-months ending 31 December 2022.

Financial Highlights:

- Revenue from customers for the half was A\$4.15 million, which is double what was reported in the corresponding prior period (H1FY22: A\$2.05 million).
- A\$1.96 million receivable from the R&D tax incentive, representing 43.5% of GTG's eligible R&D expenditure for the 2022 financial year.
- Successful US\$5 million (A\$7.2 million approx.) capital raising, before direct placement expenditures, post half-year-end.

Strategic & Operational Highlights:

- Established a strategic alliance with QIAGEN, forming a wide range of commercial opportunities for GTG with greater automation and increased capacity supporting long-term revenue growth.
- GTG set to launch the first Comprehensive Risk Test for Breast and Ovarian Cancer through the Business-to-Business ('B2B') and Consumer Initiated Testing ('CIT') channels in the United States.
- Clinical utility validated by the peer-reviewed journal *Breast Cancer Research & Treatment* highlights geneType ability to detect breast cancer earlier and outperformed commonly used clinical models (Gail and IBIS models).
- Progression in B2B channels in the United States with ten active engagements with different payer groups embarking the initial process for reimbursement coverage.

Commercialisation plans are well underway

geneType

The geneType team has made major developments over the period. Firstly, GTG has at least ten active engagements with several payer groups across the US, covering over of 42 million lives. Notably, these engagements will be the key factor in obtaining reimbursement for geneType tests, ultimately boosting sales and accelerating the adoption process in the US. Additionally, the team is also currently engaging with several Key Opinion Leaders ('KOL'). These KOL are leaders in their respective fields specific to woman medical health, garnering their support for geneType's risk assessment test implementation will build the pathway connections with other medical practices and increase the number of patient referrals to GTG. The discussion with KOL and payer groups is well underway supported by the Budget Impact Model, which highlighted a potential US\$1.4 billion health and economic benefit associated with the implementation of the geneType Breast Cancer Risk assessment test.

In Australia, GTG has been increasing partnerships with general practitioners (GP) and sales efforts with the Virtual Sales Rep and face-to-face engagement via the MedLab Medical Science Liaison team. To date, GTG has partnered with over 90 medical practices across Australia, who are actively assessing geneType platform and providing referrals to their patients.



Direct to Consumer (DTC)

EasyDNA and AffinityDNA's revenue base continue to grow. EasyDNA has focused on developing the Direct-to-Consumer (DTC) channel, which targets the growing DTC genetic testing market (global market expected to grow to US\$2.6 billion by 2025¹). EasyDNA is set to relaunch a new EasyDNA website with an embedded eCommerce platform to boost online sales and improve overall customer experience.

Commercialisation opportunities with global molecular testing leader, QIAGEN

Recently, GTG announced forming a strategic alliance with QIAGEN, developing a 'Centre of Excellence facility in Australia showcasing the Life Science and Diagnostics expertise of both organisations. QIAGEN has operations in 35 countries and the alliance is expected to provide GTG greater automation with increased capability to support higher testing demand in the future. Additionally, this partnership would support the wide-ranging cancer and serious diseases testing offerings by geneType, including the recently announced Comprehensive Risk Test for breast and ovarian cancer, creating a gateway for reimbursement coverage for these assessment tests.

Publication in scientific journals and presented at prestigious medical conferences

GTG has made a concerted effort to publish geneType risk assessment findings in peer-reviewed scientific journals and present them at prestigious medical conferences. These publications and presentations highlight clinical utility and validity of the geneType tests among medical physicians. The increased awareness among medical physicians forms a key strategy of GTG to increase the support for the adoption of the geneType platform in the medical space.

In the past six months GTG has published three separate peer-reviewed papers in scientific journals which covered the geneType test specifically for breast cancer, ovarian cancer, cardiovascular diseases, and type 2 diabetes. These publications included the peer-reviewed journal *Breast Cancer Research and Treatment* demonstrating geneType's ability to detect breast cancer earlier and outperformed its risk prediction compared to the commonly used clinical models, namely Gail and IBISv7. In addition, the publication has also highlighted geneType had comparable performance to the more complex Rosner model, with geneType having an advantage of a simpler data collection process making it a better choice for adoption in general practices.

Earlier this year, Dr Erika Spaeth, GTG's director of clinical and Scientific Affairs, presented at the prestigious American Society of Clinical Oncology Gastroenterology Cancer Symposium (ASOGI), showcasing the geneType model and its improved performance in identifying patients at risk for colorectal cancer.

Outlook

Commenting on the outlook, Simon Morriss said: "Our revenue has doubled since last year, with our DTC business is progressing well as we focus on strengthening our distribution channels and entry into regions. We have a clear and progressive path to commercialisation for geneType risk assessment tests and we continue to innovate our genomics-based technologies. We appreciate the support of our shareholders, partnering firms, and employees for their ongoing support and we look forward to sharing our continued progression."

Investor Webinar held on 28 February 2023

GTG's CEO, Simon Morriss, and CFO, Tony Di Pietro will host the investor webinar, present GTG's Half-year results, and includes a Q&A session following the release of the results.

Date: Tuesday, 28 February 2023 (Monday, 27 February, New York Time)

Time: 9am AEDT (5pm New York Time)

 $^{^{1} \} Source: https://www.technavio.com/report/direct-to-consumer-genetic-testing-market-size-industry-analysis?nowebparts and the state of the s$



Registration Link:

Participants are encouraged to register before the webinar using the details below. https://us02web.zoom.us/webinar/register/WN 06dvKDd7SCSD0Ceh5wCnNw

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

Enquiries

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About Genetic Technologies Limited

Genetic Technologies Limited (ASX: GTG; Nasdaq: GENE) is a diversified molecular diagnostics company. A global leader in genomics-based tests in health, wellness and serious disease through its geneType and EasyDNA brands. GTG offers cancer predictive testing and assessment tools to help physicians to improve health outcomes for people around the world. The company has a proprietary risk stratification platform that has been developed over the past decade and integrates clinical and genetic risk to deliver actionable outcomes to physicians and individuals. Leading the world in risk prediction in oncology, cardiovascular and metabolic diseases, Genetic Technologies continues to develop risk assessment products. For more information, please visit www.genetype.com

Forward Looking Statements

This announcement may contain forward-looking statements about the Company's expectations, beliefs or intentions regarding, among other things, statements regarding the expected use of proceeds. In addition, from time to time, the Company or its representatives have made or may make forward-looking statements, orally or in writing. Forward-looking statements can be identified by the use of forward-looking words such as "believe," "expect," "intend," "plan," "may," "should" or "anticipate" or their negatives or other variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical or current matters. These forward-looking statements may be included in, but are not limited to, various filings made by the Company with the U.S. Securities and Exchange Commission, press releases or oral statements made by or with the approval of one of the Company's authorized executive officers. Forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. As forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause the Company's actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause the Company's actual activities or results to differ materially from the activities and results anticipated in such forward-looking statements as detailed in the Company's filings with the Securities and Exchange Commission and in its periodic filings with the ASX in Australia and the risks and risk factors included therein. In addition, the Company operates in an industry sector where securities values are highly volatile and may be influenced by economic and other factors beyond its control. The Company does not undertake any obligation to publicly update these forward-looking statements, whether as a result of new information, future events o



World leading portfolio

Most comprehensive guideline driven portfolio for human and animal health.

- Patented GeneType Multi Risk Test
- Non-Invasive Prenatal Testing (NIPT)
- Carrier screen testing
- Pharmacogenomics
- Oncogenetic diseases
- Pet care

Revenues anchored by our 3 brands to seize a multi Billion-dollar opportunity.











Comprehensive genomics-based testings

via a multi-brand strategy

Medical & Payer Business to Business (B2B)



geneType

Oncology - GTG Cardiovascular **Prenatal NIPT** Carrier testing Clinical & Molecular Metabolic

Consumer initiated testing (CIT)

with medical supervision

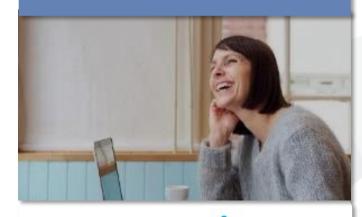




Expanded Carrier testing & NIPT Oncology - MultiTest Cardiovascular - MultiTest Metabolic – MultiTest **COVID Rick Test** Pharmacogenomics

Direct to Consumer Testing (DTC)

with no medical supervision





EasyDNA



Ancestry Paternity Health & Wellbeing Pharmacogenetics

Animal Drug testing Relationship **DNA Storage**

geneType

Global Overview

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57

Employees globally

14

Test Categories

40

Countries

51

Test

25

Patents Granted*
(9 Pending
Worldwide*)

12

Partner Laboratorie



Snapshot and Achievements last 12 months

GeneType commercialization

- Phase 1 commercial release of the geneType Multi-Risk test in US
- √ 90 medical practices on-boarded launching the foundation of geneType Hubs in Australia
- ✓ Presentations by Dr Erika Spaeth at:
 - ✓ ASCOGI Cancers Symposium Jan 2023
 - ✓ San Antonio Breast Cancer Symposium,
 - ✓ Precision Medicines leaders summit
 - ✓ Precision Medicine World Conference

Partnerships

- ✓ Launch with A/Prof Charles Siles providing immediate access to more than 1,000 referring primary care physicians and 15,000 patients annually in Australia
- Partnerships with Australian Breast Care Centre and Dr Nicole Yap
- ✓ Launch of screening for breast cancer risk with Prof Bruce Mann at Royal Women's Hospital in Melbourne

EasyDNA & Affinity DNA

- ✓ Completed 2 Acquisitions
- ✓ NEW EasyDNA Website ready for launch
- ✓ NEW eCommerce Platform ready launch
- ✓ Launch Carrier Testing and Non-Invasive Prenatal Tests (NIPT) into Europe
- Partnering in India with stud farms extending paternity infrastructure into the equine industry
- ✓ Launch DNA storage solution in GTG NATA approved facility

Reimbursement activation

- ✓ Independently developed Budget Impact Model (BIM) identifies US\$1.4 billion dollars in annual saving by ALVA 10
- 10 Active payer conversations
- Progress on US Payer meetings to enable coverage across millions of lives

Clinical Validity and IP Strategy

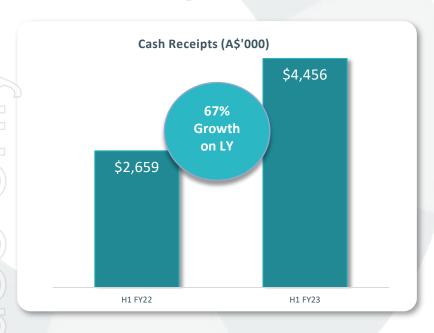
- ✓ Published in PLOS ONE
- ✓ Published in Journal or Precision Medicine
- ✓ Published in European Journal of Cancer prevention
- Published in journal Breast Cancer Research and Treatment
- √ 25 Patents granted or pending
- 4 papers published
- √ 3 papers under review

Laboratory Capability

- Gained NATA and CMS-CLIA accreditation and certification for 6 polygenic risk score tests
- Successful ARTG notification to TGA for company IVDs for all tests on the multi-risk test



Delivering Revenue and Growth – H1 FY23



H1 CASH RECEIPTS

A\$4.5m

CASH BALANCE

A\$12.4m*

GROSS MARGIN

A\$2.03m

GROSS MARGIN

45%

Strategic and Operational Highlights:

- Cash receipts from customers A\$4.5m +67% on last half-year;
- 6 consecutive qtrs. of growth on prior year
- R&D Tax Incentive of A\$1.96m received in Q3 2023
- Strategic Partnership launched with QIAGEN global diagnostics

- Invited to India and UAE as guests of MedAchievers to explore GeneType MultiTest launch strategy
- GeneType Risk Test outperforms traditional risk assessments for breast cancer in identifying risk by up to 9 times
- 10 active engagements with U.S. payer groups, with a combined coverage of 42 million lives, including insurers, payers, and Key Opinion Leaders (KOL's)
- Presentations at ASCG Gi Cancers Symposium in San Francisco





Core '4'



Execute the B2B commercialisation of the geneType multi-risk test



Demonstrate clinical validity & clinical utility of geneType tests



EasyDNA & Affinity DNA Revenue Growth: Tests, Channels. & Markets



Innovation: Next Generation of capability – Starting with Epigenetics









NEW Strategic Alliance with Qiagen

The alliance will establish and develop a 'Centre of Excellence' facility in Australia



QIAGEN will support the enhancement of GTG capabilities through software, hardware, consumable and technical solutions, including:

- Reagents and QIAGEN's proprietary QCII software to complete Next Generation Sequencing (NGS) validation in house.
- The rollout will include QIAGEN's QIAseq targeted DNA Pro Sample to Insight solutions for NGS Oncology and customized inhouse data analysis tools to provide sample to result service for GTG customers









NEW Comprehensive Breast and Ovarian Cancer test

Evaluates a woman's risk of developing Breast and/or Ovarian Cancer in women 30 years+

5% - Hereditary Cancer with known pathogenic variant BRCA1/2



10% - Familial cancer with no known pathogenic variant



85% - GeneType Patented integrated Breast and Ovarian Risk test





- The test evaluates a women's risk of developing Breast and/or Ovarian Cancer either from a hereditary genetic mutation or from the far more common familial or sporadic cancer. (Announced Feb 3, 2023)
- GTG's unique approach "appends" the detection of the 13 major "actionable" Breast and Ovarian cancer susceptibility genes to the GeneType test platform.
- Advances the goal of providing population-based genetic screening where up to 85% of cancers diagnosed do not have hereditary or family history
- Showcase at BRCA 2023 in Montreal





GeneType Priority Pathway to Market



Medical & Payer Business to Business (B2B)

Health Economic modeling completed by ALVA10*

Certifying reimbursable testing platform: BRCA test & LYNCH Syndrome test

A plan curated for: Payers / Insurers*
Primary Care Physicians, Specialists, Surgeons,
Concierge Medicine Groups

geneType Multi-test

NGS platforms with Germline, Carrier Screening and NIPT

BRCA test & LYNCH Syndrome test



Payer coverage is the key driver of revenues for geneType

Coverage from payers in the US will accelerate adoption of geneType Risk Assessment Tests more widely

Budget Impact Model (BIM) demonstrates significant health & economic benefits of implementing the geneType Breast Cancer Risk Assessment Test

11 Active conversations with payer groups in the US

US Payers include:

- Humana 17 million lives covered
- Aetna 22.1 million live covered
- Independence Blue Cross 3 million lives covered

Smaller payers such as employer groups have potential to move quickly

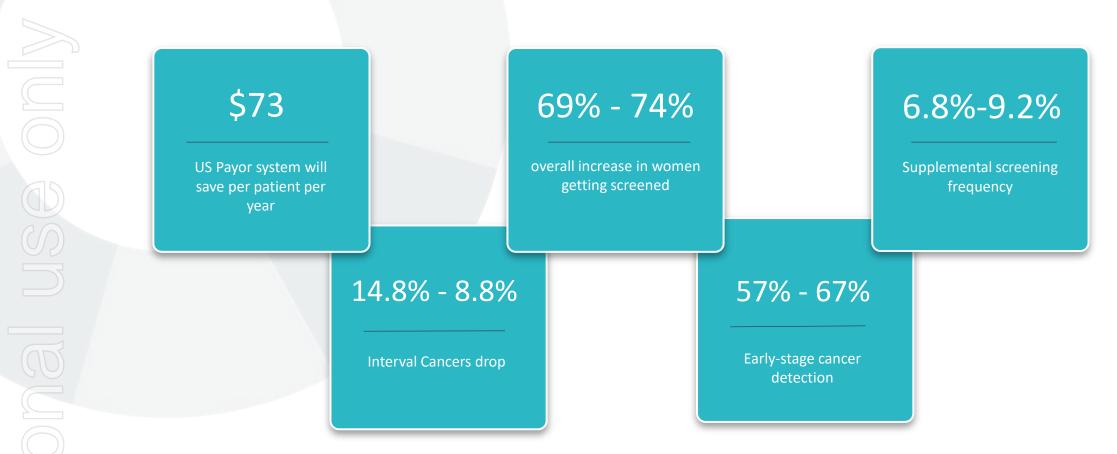
BIM validates the benefits of implementing geneType

^{*} Corporates and Insurance market entry assessment in progress and Health Economic Model being completed by ALVA10.



Economic Modeling in the US Payer System¹

The economic benefit to the payers in the US is US\$1.4B per annum



3.6% in annual savings to a payer system in the screening and treatment of breast cancer.





DTC - Growth strategy for EasyDNA

PHASE 1 Brand Re-Ignition



Brand Refresh

Multi-brand Portfolio

EasyDNA Brand Refresh

Test Rationalization





Website Refresh

Website Development

First-party data collection

Targeted Messaging

Improve User experience and engagement

PHASE 2 Revenue and Growth Focus



Improved Lead Gen

Google Ads Facebook Ads

Content & Email Marketing

Influencer Marketing & Testimonials



New Sales Channels

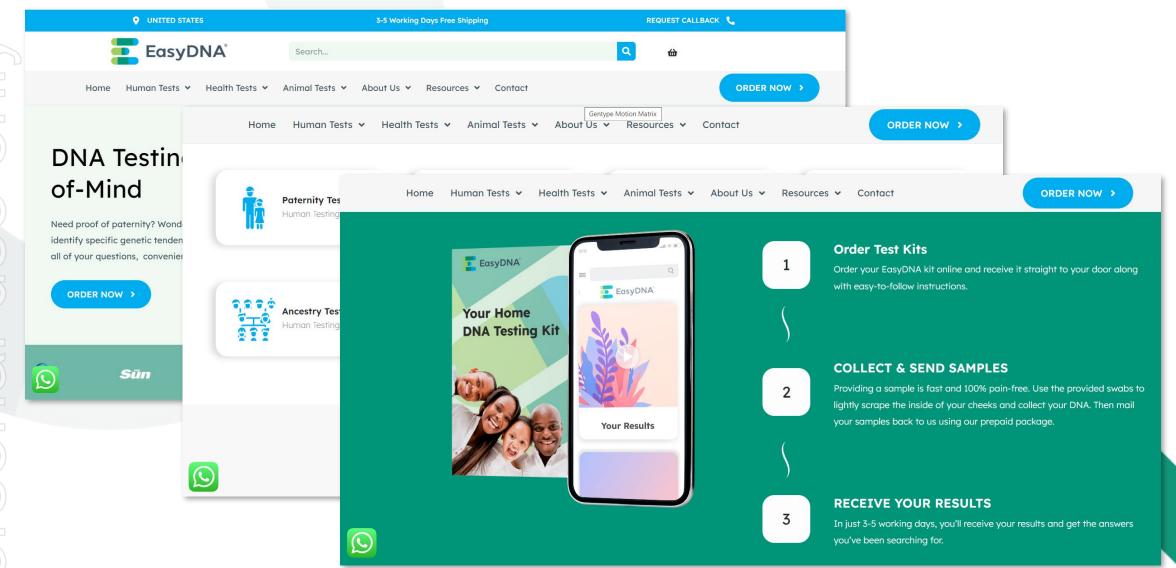
Amazon store front

Target B2B customer segments

New Markets



eCommerce Growth strategy for EasyDNA



Thank you

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Board and Management: Sales and Scientific expertise leading GTG



Mr. Peter Rubinstein
BEc, LLB
Chairman
Non – Executive Director



Dr. Lindsay WakefieldMBBS
Non – Executive Director



Mr Nick Burrows
B.Comm, FAICD, FCA, FGIA,
FTIA, F Fin
Non – Executive Director



Simon Morriss
GAICD
Chief Executive Officer



Dr. Jerzy "George" MuchnickiMBBS
Non-Executive Director



Erika SpaethPhD
Director of Clinical & Scientific
Affairs



Richard Allman BSc, PhD Scientific Advisor



Tony Di Pietro

B. Comm, CA, AGIA, MAICD

CFO & Company Secretary



Carl StubbingsChief Commercial Officer



Strong Scientific Leadership: Advisory Board



Professor Jon Emery

MBBCh MA DPhil FRACGP MRCGP
Research & Education Lead, Primary Care
Integration, Victorian Comprehensive
Cancer Centre Herman Chair of Primary
Care Cancer Research, University of
Melbourne



Professor Finlay Macrae AO

MBBS, MD, FRACP, FRCP, AGAF MWGO is Principal Fellow and Professor, Department of Medicine, University of Melbourne, and Head of Colorectal Medicine and Genetics, The Royal Melbourne Hospital



Ora K. Gordon, M.D.

MD, MS, FACMG Regional Medical Director, Center for Clinical Genetics & Genomics. Clinical Director, PSJH Population Health Genomics Program. Chair, Integrated Network Cancer Program, Professor of Genetics, St John Cancer Institute



A.Prof Ron 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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Financial Overview

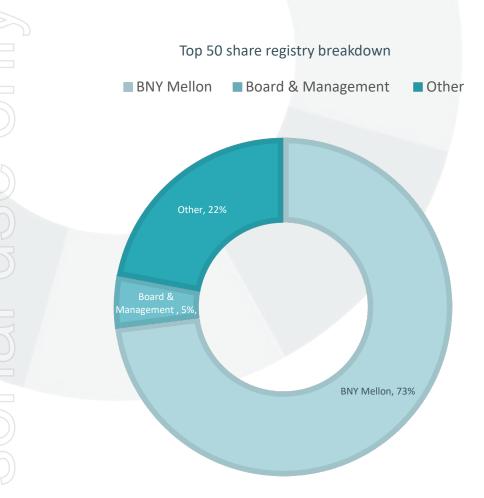
- Net cash outflow of A\$6.7 million in H1 FY'23 (compared to H1 FY'22 outflow of: A\$7.6 million) as we continue to grow EasyDNA and Affinity DNA brand sales and develop and commercialise our geneType tests
- Cash reserves will be directed to:
 - to support the commercialisation of the GeneType Multi Risk test through the B2B channels with payers, insurers and employers in the United States and expand into Europe;
 - to drive new market opportunities in reimbursable categories by leveraging our strategic relationship with QIAGEN;
 - for funding product research and development;
 - to increase our sales and marketing presences and drive of its tests via the consumer-initiated testing platforms;
 - to execute the go to market, sales and marketing to launch the Comprehensive Hereditary Breast and Ovarian Cancer Risk Test as part of our germline genetic testing division; and
 - for other working capital and general corporate purposes.

A\$'000	31-Dec-22	31-Dec-21	Change
Net operating cashflow	(6,132)	(4,137)	-48%
Receipts from customers	4,456	2,659	67%
Cash	5,045	13,507	-63%

¹ Based on cashflow projections



Corporate Overview



Dual Listed on the ASX and Nasdaq			
Financial Information			
Share price (AUD) as at 24 February 2023	0.4c		
ADR price (USD) as at 24 February 2023	\$1.27		
Ord Shares on Issue (M)	11,542		
ASX 52-week trading (AUD low/high)	0.2/1.3c		
Nasdaq 52-week trading (USD low/high)	0.83/2.40		
Market Cap (A\$M/US\$M)	46.17/19.55		
Cash at 31 December 2022	A\$5.0m		
Cash at 30 June 2022	A\$11.7m		
Debt (30 June 2022 and 31 December 2022)	nil		



Our Intellectual Property

4 Patents granted in the US

- Patent No: US 11,257,569, Methods of assessing risk of developing a severe response to Coronavirus infection
- Patent No: US 11,072,830, Methods for breast cancer risk assessment
- Patent No: US 10,683,549, Methods for assessing risk of developing breast cancer
- Patent No: US 10,920,279, Methods for assessing risk of developing breast cancer

2 Patents granted in PRC (China & HK)

- Patent No. 201080033130.5 Methods for Breast Cancer Risk Assessment
- Patent No. 201580063966.2 Methods for assessing risk of developing breast cancer

9 Patent families pending

- Breast cancer risk assessment
- Methods for assessing risk of developing prostate cancer
- Methods for assessing risk of developing ovarian cancer
- Methods of assessing risk of developing a severe response to Coronavirus infection
- Methods of assessing risk of developing a disease
- Methods for assessing risk of developing breast cancer
- Improved methods for assessing risk of developing breast cancer
- Methods of assessing risk of developing breast cancer
- Methods for assessing risk of developing colorectal cancer

* Patents granted are specific to the GeneType portfolio of products



Defined Terms

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.

Polygenic risk score - a number associated with one's disease risk based on the aggregated effects of individual risk variants through a multiplicative algorithm.

Variant - Single Nucleotide polymorphism (SNP), an alteration in DNA that may be a common or rare event.

Genomic - pertaining to function of genetics from structure to relationship between genetic events.

Genetic - pertaining to a gene.

GWAS - genome-wide association studies are 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.

SNP - Single nucleotide polymorphisms, frequently called SNPs (pronounced "snips"), are 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 withs its associated morbidities and mortalities.

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.

Clinical Laboratory Improvement Amendments (CLIA) - Regulates laboratory testing and require clinical laboratories to be certified by the Center for Medicare and Medicaid Services (CMS) before they can accept human samples for diagnostic testing

National Association of Testing Authorities (NATA) - the authority responsible for the accreditation of laboratories, inspection bodies, calibration services, producers of certified reference materials and proficiency testing scheme providers throughout Australia. It is also Australia's compliance monitoring authority for the OECD Principles of GLP. NATA provides independent assurance of technical competence through a proven network of best practice industry experts for customers who require confidence in the delivery of their products and services.

Next Generation Sequencing (NGS) — Next-generation sequencing (NGS), also known as high-throughput sequencing, is the catch-all term used to describe a number of different modern sequencing technologies. These technologies allow for sequencing of DNA and RNA much more quickly and cheaply than the previously used Sanger sequencing, and as such revolutionised the study of genomics and molecular biology.

Laboratory Developed Tests (LDT) - A type of in vitro diagnostic test that is designed, manufactured and used within a single laboratory.

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.

Health Care Professionals (HCP) – physician, GP, or specialist authorized to receive the patient results