



# Genetic Technologies Business Update

September 8, 2022

Authorised by the Board of Directors of Genetic Technologies Limited

ASX: GTG  
NASDAQ: GENE

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# Our Overview

## Vision and World Leading Portfolio

Unlocking personalised preventative health

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## Markets & Global Presence

Expansion to over 40 countries with a multi brand strategy

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## Key Operating Insights

Financial and Strategic highlights

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## Focus Areas and Market Opportunity

Seizing a Multi-billion dollar opportunity

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## Pathways to Market

Brand segmentation and distribution channels

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## Patented Innovation and Divisions

Cutting edge technology

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# Unlocking personalised preventative medicine

Genetic Technologies has the most comprehensive and guideline driven portfolio. Transforming the conversation from a one-size-fits-all model to **personalised, preventative health**

Where each person has the information, they need to manage their health according to their own risk.

Empowering physicians to improve health outcomes for people around the world.

Tracking disease to its source and enabling a new era of personalised medicine.



# 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.



# Patented\* integrated risk testing for a range of critical medical conditions

Genetype tests integrate individual's familial, clinical and genetic information into actionable clinical insights.

Combining genetic and clinical risk models with cutting-edge research, we're leading a personalised healthcare revolution.

Our medical practitioners, scientists and technicians have developed the next generation of integrated predictive genetic testing and assessment tools – empowering physicians and patients to proactively manage health.

- ✓ 10 Patent families covering the GeneType products
- ✓ 4 Patents granted in the US
- ✓ 2 Patents granted in China
- ✓ 9 Patents pending Worldwide



## Unequaled experience

Scientific team leveraging their extensive research track record in breast and colorectal to expand our medical-grade genetic test portfolio into further cancers and chronic conditions.



## Relentless innovation

Accelerating the world's transition to personalised, preventative health care by converting genetic data into actionable solutions for consumers and doctors.



## Leading integrated technology

The proprietary integration of genomic and clinical risk factors delivers the most complete risk assessments for serious diseases in the world – the foundation of geneType.



## Setting new standards

Setting clinical, safety and ethical standards to ensure the best health outcomes.

# Global Overview



57

Employees  
globally

40

Countries

25

Patents  
Granted\*  
(9 Pending  
Worldwide\*)

14

Test  
Categories

51

Tests

12

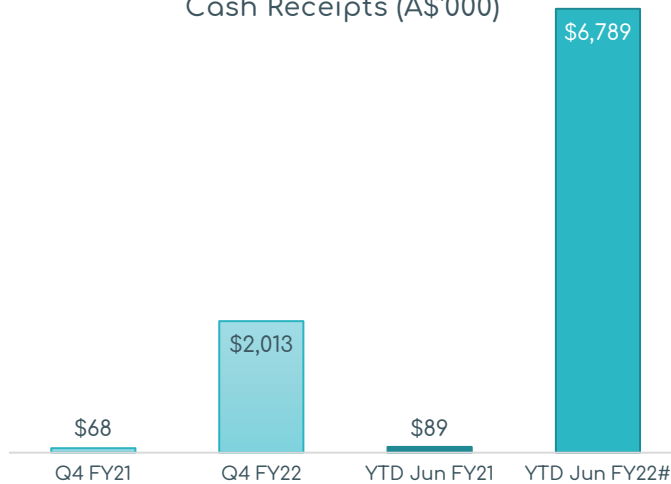
Partner  
Laboratories

\* Patents granted are specific to the GeneType portfolio of products



# Delivering Revenue and Growth June Qtr FY22

Cash Receipts (A\$'000)



REVENUE

A\$2.01m

CASH BALANCE

A\$11.7m\*

GROSS MARGIN

A\$1.0m

GROSS MARGIN

51%

## Strategic & Operational Highlights:

- Full year receipts from customers A\$6.8m with 4 consecutive qtrs. of growth on prior year
- Completed independently developed Budget Impact Model (BIM) demonstrating US\$1.4b in potential savings for US payers annually
- Initiated discussions with national payers in the US for GeneType risk tests
- GeneType Multi-Risk Test is implemented in 24 clinics building our geneType hub strategy
- EasyDNA entered the European market with carrier testing and Non-Invasive Prenatal Test (NIPT) and launches DNA storage strategy
- EasyDNA entered India's equine industry with stud farm partnerships broadening its paternity infrastructure
- Successful ARTG notification to TGA for company IVDs for all test on the Multi-Risk test

\*June '22 quarter end cash and cash equivalents of A\$11.7 million

# All revenues for 2021 - 2022 are 'out of pocket' our strategy for reimbursement should become effective in 2022 - 2023 FY

# Our FOCUS

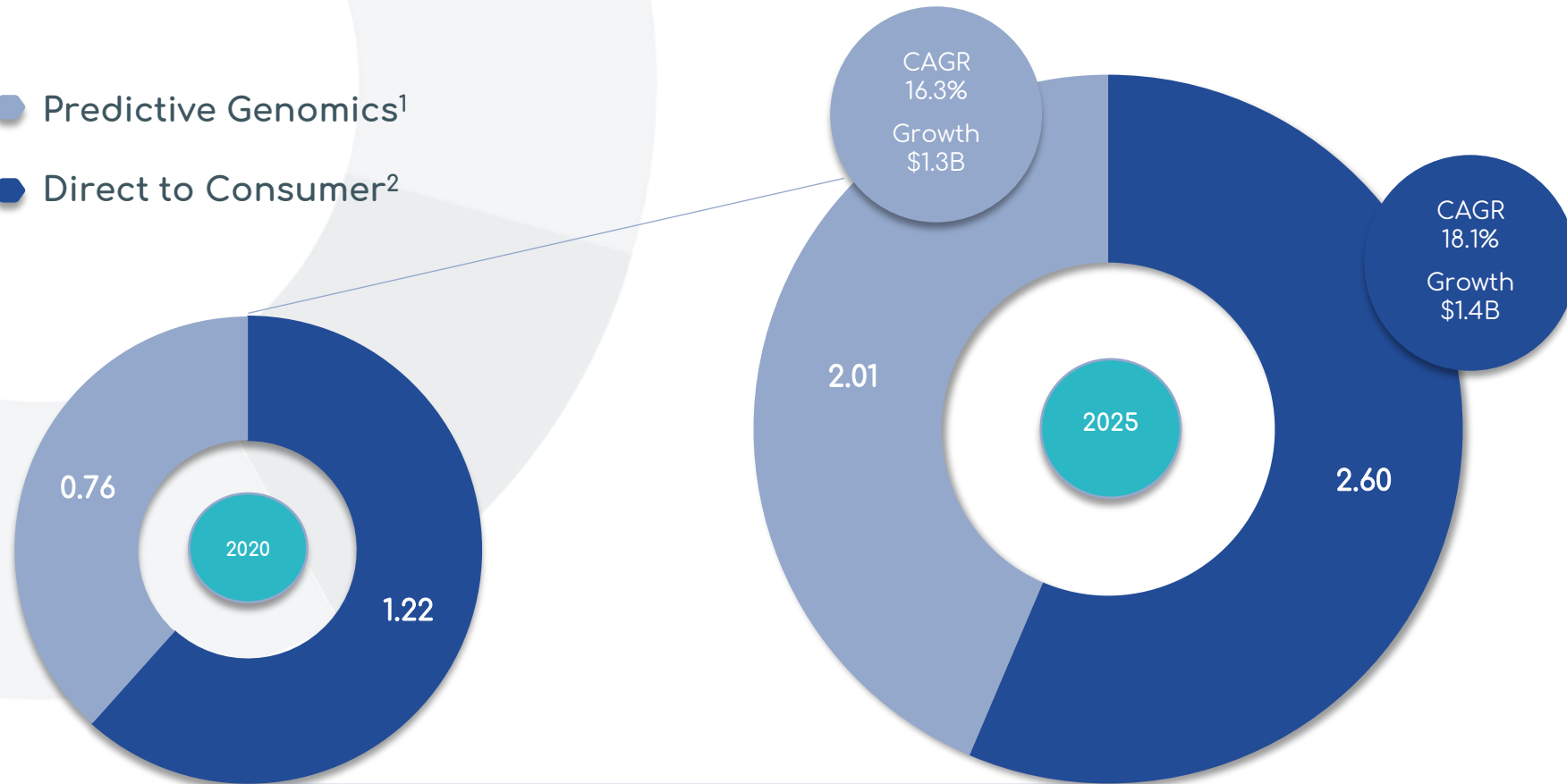
## Core '4'

-  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

# Market Size and Opportunity

Estimated Global Revenue growth is US\$2.8B in to 2025

- Predictive Genomics<sup>1</sup>
- Direct to Consumer<sup>2</sup>



US\$ 'Billion

US\$ 'Billion

1. Newsire - Predictive Genetics Market Research Report by Type, by Demographics, by Test Type January 6 2022  
 2. Technavio Market Research reports - Direct-To-Consumer Genetic Testing Market by Distribution Channel, Service, and Geography - Forecast and Analysis 2021-2025

# Our Innovation – Multi-Risk Test

GeneType can identify patients 'at risk' before onset and aid in the early detection and treatment.

GeneType Risk assessment test for breast cancer has demonstrated improved early stage detection by 18% and saving approx. US\$1.4B per annum<sup>4</sup> for the US payer

GeneType Multi-test covers >70% of mortality & morbidity

## Diseases Areas

### Oncology

Breast Cancer  
 Colorectal Cancer  
 Prostate Cancer  
 Melanoma  
 Pancreatic Cancer  
 Ovarian Cancer



Phase 1 Launch <sup>2</sup>

### Cardiovascular

Atrial Fibrillation  
 Coronary Artery Disease

### Metabolic

Type 2 Diabetes



Phase 2 Launch <sup>3</sup>

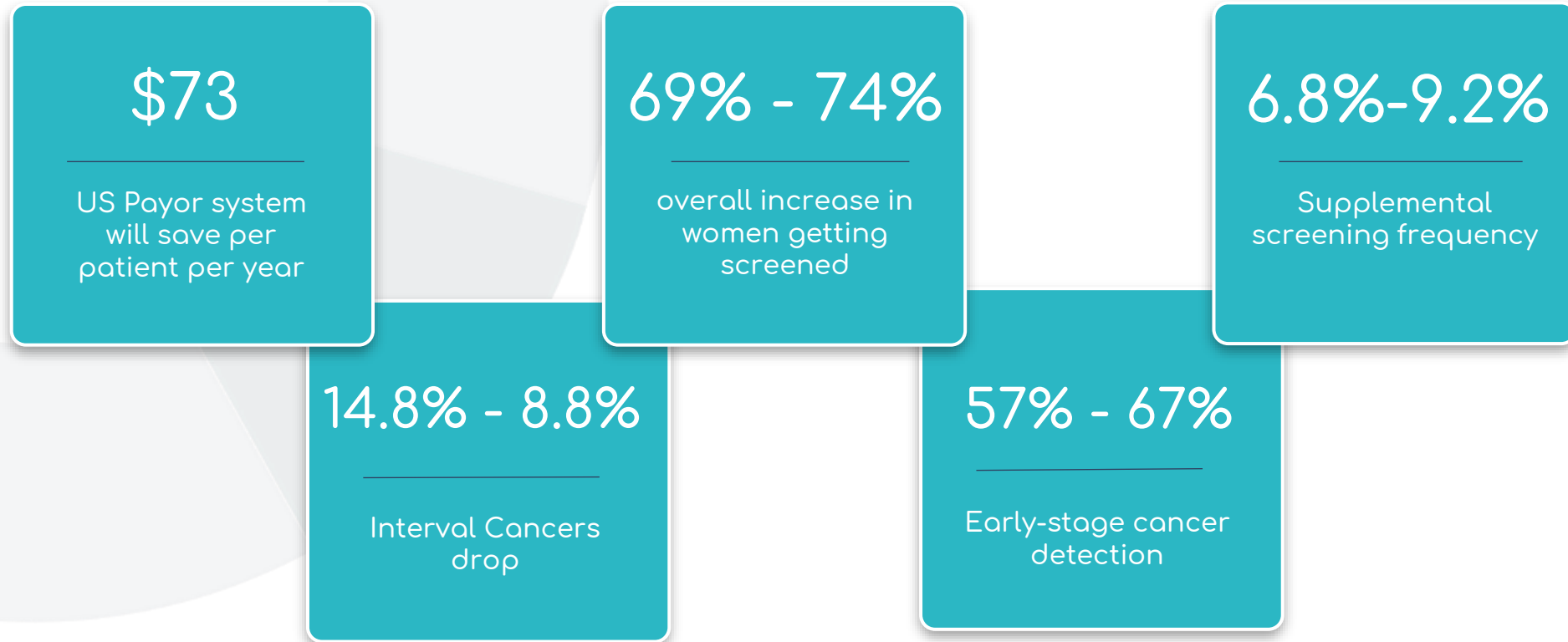


NEW Universal sample collection kit with TGA, FDA and EU regulatory approval<sup>1</sup>

1. TGA, FDA and EU regulatory approval granted to the sponsor, DNA Genotek
2. Commercial availability expected Q1 CY2022
3. Commercial availability upon regulatory approval
4. Budget Impact Model prepared by Alva10

# Economic Modeling in the US Payer System<sup>1</sup>



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

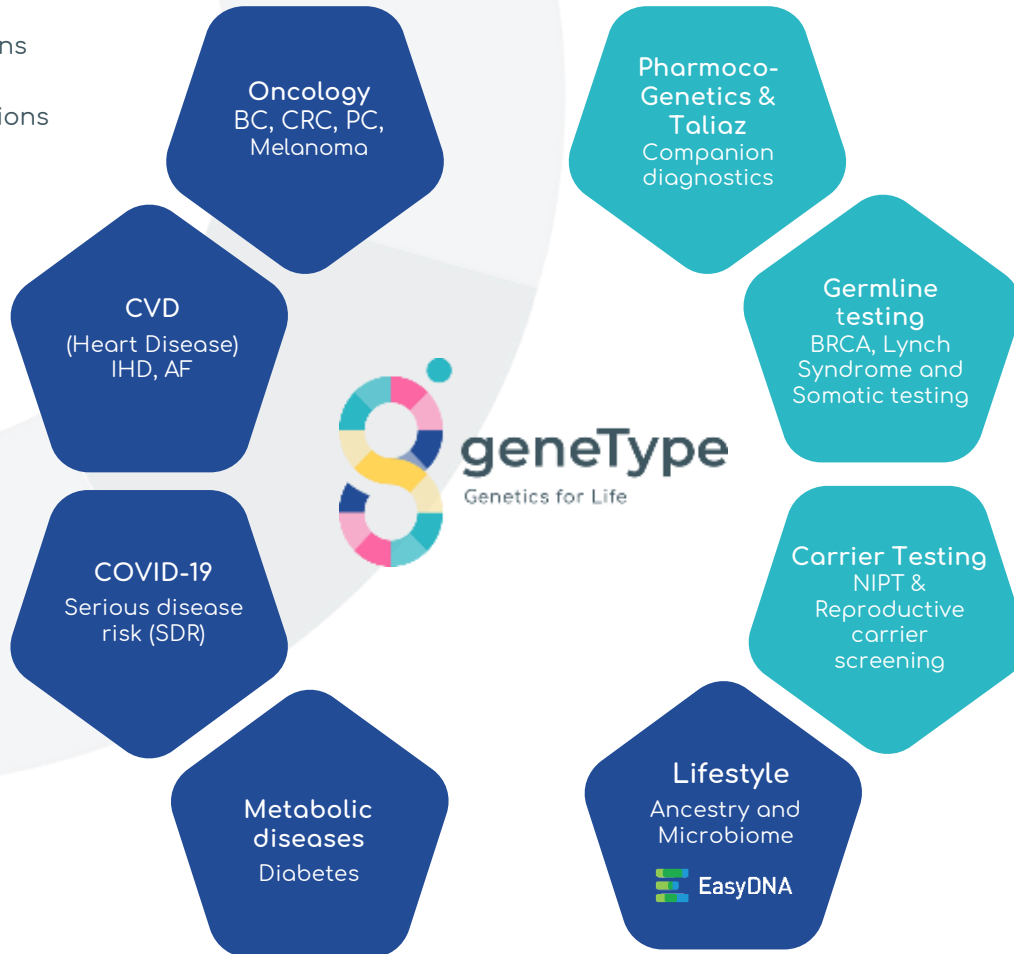


3.6% in annual savings to a payer system in the screening and treatment of breast cancer.



# Divisions of Operations

-  Existing divisions
-  Emerging divisions



**NEW**  
Universal  
collection test kit  
to support Multi  
Test Launch



NEW Universal sample collection kit with TGA, FDA and EU regulatory approval<sup>1</sup>

BC = Breast Cancer; CRC = Colorectal Cancer; PC = Prostate Cancer; CVD = Cardiovascular Disease; IHD = Ischemic Heart Disease; Atrial Fibrillation  
1. TGA, FDA and EU regulatory approval granted to the sponsor, DNA Genotek

# Pathways to Market

Executing a multi-brand strategy

## Medical & Payer Business to Business (B2B)



Oncology - GTG  
 Cardiovascular  
 Prenatal NIPT and Carrier testing  
 Clinical & Molecular  
 Metabolic  
 Taliaz Predictix

## Consumer initiated testing (CIT) with medical supervision



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

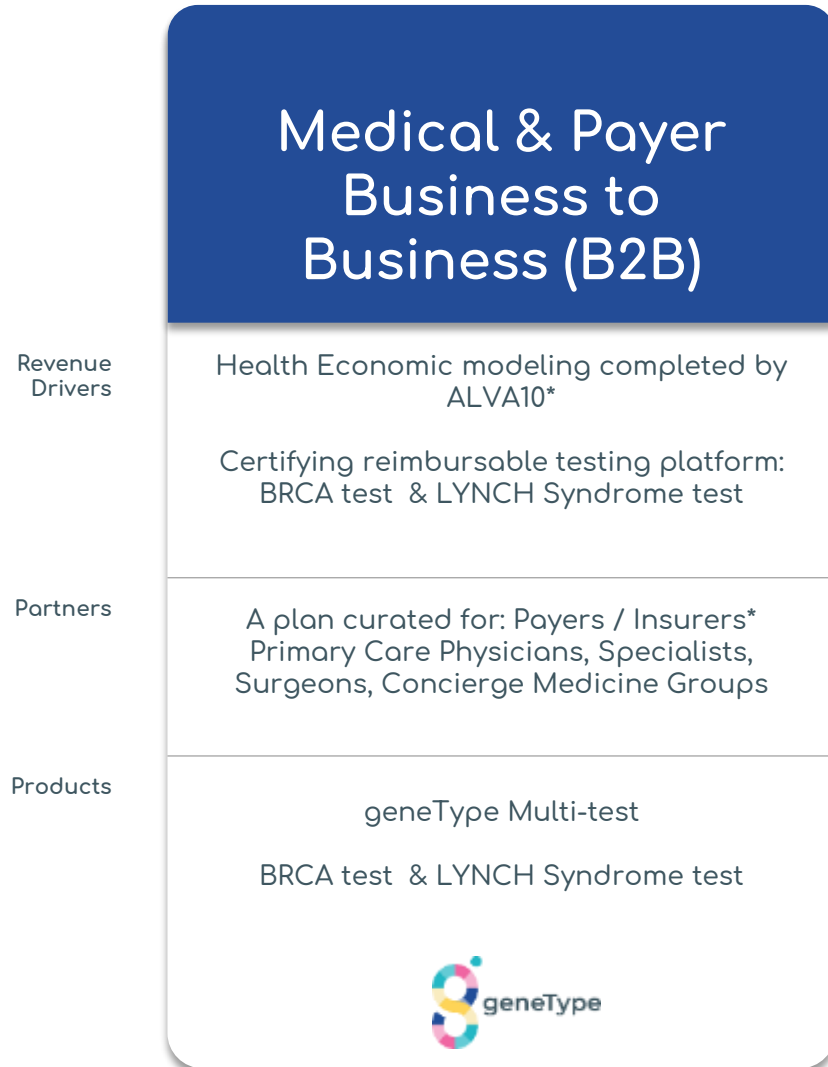
## Direct to Consumer Testing (DTC) with no medical supervision



Ancestry  
 Paternity  
 Health & Wellbeing  
 Pharmacogenetics

Animal  
 Drug testing  
 Relationship  
 DNA Storage

# Pathways to Market – highest priority



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

BIM demonstrated significant economic benefits enabling:

- Direct engagement with a wide range of US payers
- Publication of results in respected peer reviewed journal(s)

US Payers include:

- Humana – 17 million lives covered
- Etna – 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

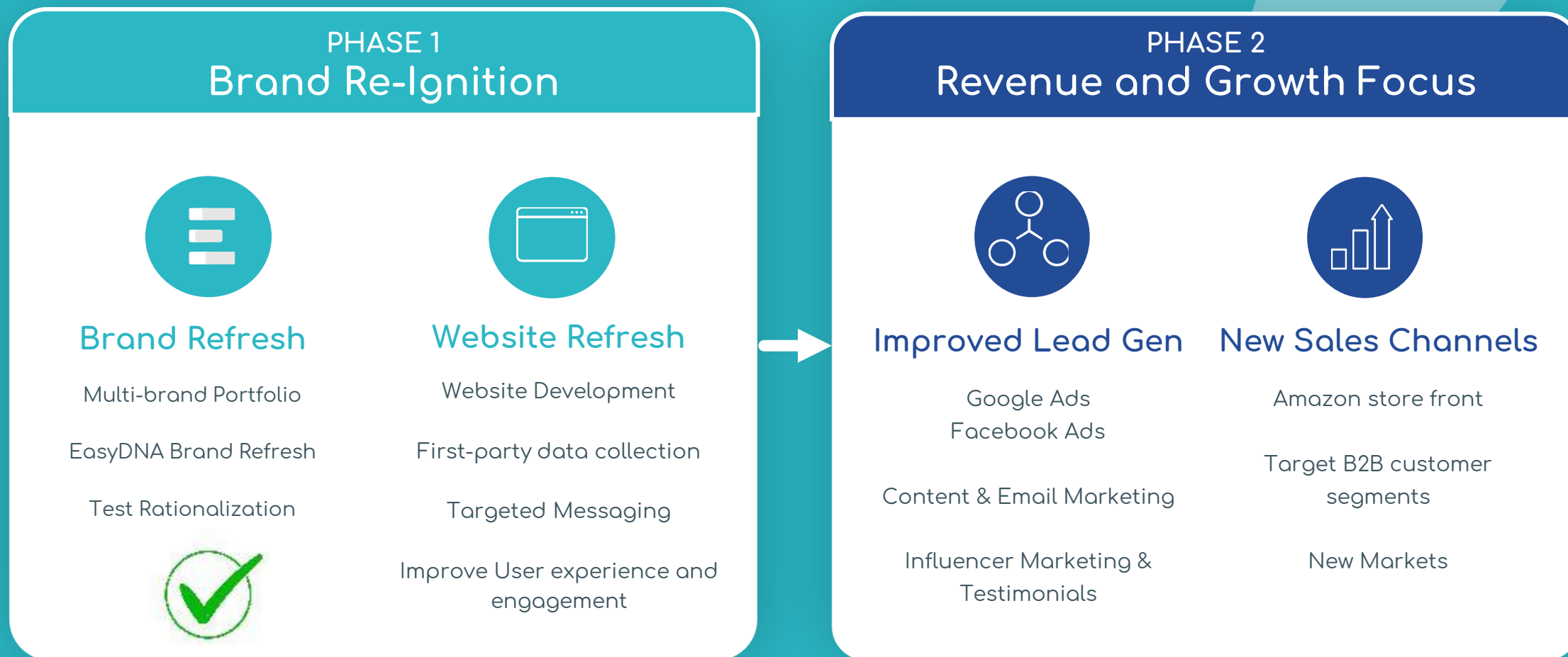
\* Corporates and Insurance market entry assessment in progress and Health Economic Model being completed by ALVA10.



# Pathways to Market

	Consumer initiated testing (CIT) with medical supervision	Direct to Consumer Testing (DTC) with no medical supervision
Revenue Drivers	<p>Building consumer awareness of serious disease test via a platform that integrates medical supervision</p> <p>Launched US and Australia CIT platforms in 2020</p>	<p>Leveraging the EasyDNA brand and platform provides the foundation to grow in 40 countries</p>
Partners	<p>Medical partners: LimsABC InTeleLabs in the US Phenix Health in Australia</p>	<p>Agreements with 12 laboratories in North America, AsiaPac and Europe</p>
Products	<p>geneType for Breast Cancer geneType for Colorectal Cancer geneType Multi-test</p> 	<p>EasyDNA paternity, ancestry, gut microbiome testing and non-medical related genomic tests</p>  

# Growth strategy for EasyDNA



# GeneType Website – ALL tests LIVE

## A leader in personalised predictive genetics



GeneType Integrated Risk, Polygenic Risk (PRS) and Clinical Risk (CRS)



Non-invasive Prenatal Testing



Intolerance Test



Inherited Monogenic Disease (Germline)



Pharmacogenetic Testing



Petgen™ Animal Test



Carrier Testing



DNA Testing (Ancestry, Paternity)



DNA Storage



buy now

# Snapshot and Achievements last 12 months

## GeneType commercialization

- ✓ Phase 1 commercial release of the geneType Multi-Risk test in US
- ✓ 24 medical practices on-boarded launching the foundation of geneType Hubs in Australia
- ✓ Completed 2 Acquisitions – EasyDNA and AffinityDNA
- ✓ Presentations by Dr Erika Spaeth at:
  - ✓ 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
- ✓ Launch of screening for breast cancer risk with Prof Bruce Mann at Royal Women's Hospital in Melbourne

## EasyDNA integration activities

- ✓ Acquisition of EasyDNA completed
- ✓ 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

## Clinical Validity and IP Strategy

- ✓ 10 Patents granted
- ✓ 5 new provisional patents filed
- ✓ 4 papers published
- ✓ 3 papers under review

## Reimbursement activation

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

## 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

A decorative graphic in the top-left corner consisting of a semi-circle divided into several colored segments: teal, pink, and light blue.

# Summary



# Thank you

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[www.linkedin.com/company/genetype-limited](http://www.linkedin.com/company/genetype-limited)

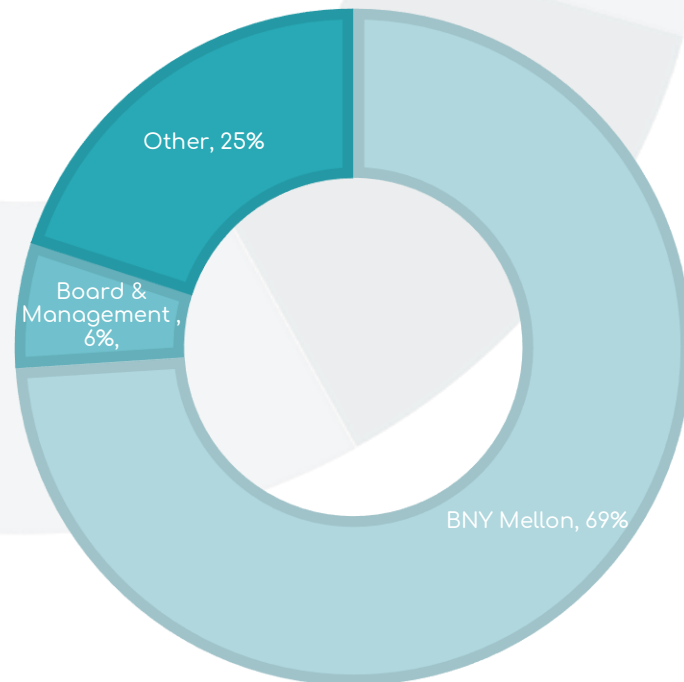
[www.genetype.com](http://www.genetype.com)

# Appendices

# Corporate Overview

Top 50 share registry breakdown

■ BNY Mellon ■ Board & Management ■ Other



## Dual Listed on the ASX and Nasdaq

### Financial Information

Share price (AUD) as at 5 September 2022	0.4c
ADR price (USD) as at 5 September 2022	\$1.39
Ord Shares on Issue (M)	9,234
ASX 52-week trading (AUD low/high)	0.3/0.9c
Nasdaq 52-week trading (USD low/high)	0.95/3.54
<b>Market Cap (A\$/US\$M)</b>	<b>36.94/22.64</b>
Cash at 30 June 2022	A\$11.7m
Cash at 31 March 2022	A\$11.4m
Debt (31 March 2022 and 30 June 2022)	nil



# Financial Overview

- Net cash inflow of A\$197k in Q4 FY'22 (compared to Q3 FY'22 outflow of: A\$2.1 million) as we continue to grow EasyDNA and Affinity DNA brand sales and develop and commercialize our geneType tests
- Cash reserves of A\$11.7 million at 30 June 2022 including the R&D Tax incentive receipt of A\$1.44 million will be directed to:
  - Support the commercialization of geneType products in United States, Europe and Australia
  - Develop the direct-to-consumer sales channel through EasyDNA and AffinityDNA
  - US Payer model development for geneType for breast cancer;
  - General product research and development; and
  - For general working capital.

A\$'000	31-Mar-22	30-Jun-22	Change
Net operating cashflow	(2,056)	197	110%
Receipts from customers	1,967	2,013	2%
Research and Development and Staff costs	1,244	1,429	15%
Cash	11,350	11,733	3%

<sup>1</sup> Based on cashflow projections

# Board and Management: Sales and Scientific expertise leading GTG



**Mr. Peter Rubinstein**  
BEd, LLB  
Chairman - Non -  
Executive Director



**Dr. Lindsay Wakefield**  
MBBS  
Non - Executive  
Director



**Mr Nick Burrows**  
B.Com, FAICD, FCA,  
FGIA, FTIA, F Fin  
Non - Executive  
Director



**Simon Morriss**  
GAICD  
Chief Executive Officer



**Dr. Jerzy "George"  
Muchnicki**  
MBBS  
Executive Director



**Erika Spaeth**  
PhD  
Director of Clinical  
Affairs & Medical  
Education



**Richard Allman**  
BSc, PhD  
Chief Scientific  
Officer



**Mike Tonroe**  
BSc, FCA, MAICD  
Chief Financial  
Officer



**Carl Stubbings**  
Chief 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.

# Collaborations

Professor Bernard  
Rosner



**HARVARD**  
MEDICAL SCHOOL

Channing Division of Network Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston, Massachusetts, USA – Principal Investigator of the Nurses' Health Study (International expert in Biostatistics and breast cancer epidemiology).

Collaborating on a project to improve the GeneType Breast Cancer Test and to Cross-validate the Ovarian cancer test in the Nurses Health Study

Professor Graham  
Colditz



**Washington University in St. Louis**  
INSTITUTE FOR PUBLIC HEALTH

Deputy Director, Institute for Public Health. Washington University School of Medicine, St. Louis, Missouri (International expert in Biostatistics and breast cancer epidemiology).

Collaborating on a project to validate the GeneType for Breast Cancer Test in African American patients

Professor John  
Hopper



**THE UNIVERSITY OF  
MELBOURNE**

Professorial Fellow at the Centre for Epidemiology and Biostatistics in the School of Population Global Health, Melbourne University

Collaborating on a project to improve the GeneType for Breast Cancer Test and on a joint project with Prof Emery to develop clinical utility evidence for the GeneType tests

# Collaborations

Professor Jon Emery



THE UNIVERSITY OF  
MELBOURNE



VCCC  
Alliance  
Overcoming cancer together

Professor of Primary Care Cancer Research at the University of Melbourne, and the Victorian Comprehensive Cancer Centre

Collaborating on a joint project with Prof Hopper to develop clinical utility evidence for the GeneType tests

Memorial Sloan Kettering Cancer



Memorial Sloan Kettering  
Cancer Center

Collaborating on a project to investigate modification of risk in BRCA-positive patients by polygenic risk scores

Ohio State University



THE OHIO STATE  
UNIVERSITY

Collaborating on a project to investigate modification of risk in BRCA-positive patients by polygenic risk scores

# 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

# 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 with 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