# Genetic Technologies

## AusBioInvest

## October 27, 2022

Authorised by the Board of Directors of Genetic Technologies Limited

ASX: GTG
NASDAQ: GENE

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# Unlocking personalised preventative medicine

Transforming the conversation from a one-size-fits-all model to
personalised, preventive health

Identify risk of serious disease before onset beyond family history.

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

Empowering physicians 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.

geneType Genetics for Life  easyDNA  AffinityDNA

* Patents granted are specific to the GeneType portfolio of products

# Patented* Genetype tests Integrate polygenic risk and clinical risks for critical medical conditions

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

A non-invasive saliva based test combines 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**

# Global Overview

**57**
Employees globally

**40**
Countries

**25**
Patents Granted*
(9 Pending Worldwide*)

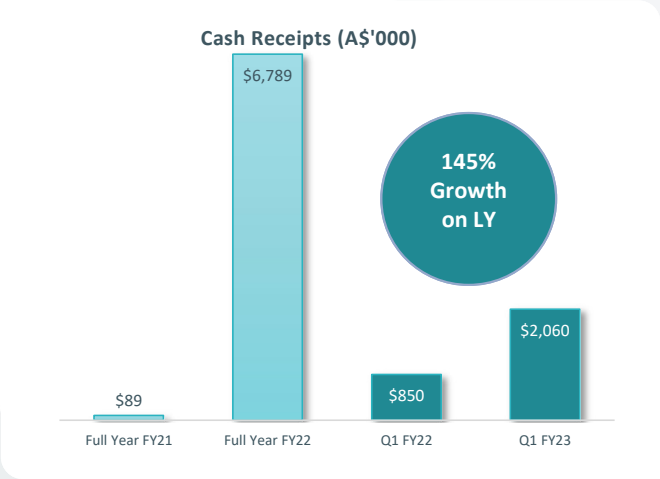
**14**
Test Categories

**51**
Tests

**12**
Partner Laboratories

* Patents granted are specific to the GeneType portfolio of products

# Delivering Revenue and Growth – Q1 FY23




| Q1 CASH RECEIPTS | CASH BALANCE |
|---|---|
| A$2.06m | A$7.9m* |
| **GROSS MARGIN** | **GROSS MARGIN** |
| A$0.9m | 44% |

**Strategic & Operational Highlights:**

- Cash receipts from customers A$2.06m with +145% on last year; Revenue A$1.93 million for the quarter, up 375% from (Q1 FY22)
- 5 consecutive qtrs. of growth on prior year
- GeneType Multi-Risk Test is implemented in 64 clinics building our geneType hub strategy
- Promoting to over 10,000 General practitioners (GPs) across Australia by leveraging Breast Cancer Awareness Month ]]
- Clinical utility demonstrated by the peer review publication of Genetype for Breast Cancer in the Journal of Precision Medicine confirming GeneType Risk Test outperforms traditional risk assessments for breast cancer in identifying risk by up to 9 times
- Engaged Jody Fassina, Insight Strategies to build long-term pathway for Australian Federal Government support for reimbursement
- Material progress in USA with Alva10 and large payer engagement
- New USA business manager is making great progress with concierge medicine groups and independent doctor network

*Sept '22 quarter end cash and cash equivalents of A$8.0 million as announced on ASX 25 October 2022
# All revenues for the period '21 & '22 are 'out of pocket' our strategy for reimbursement should become effective in 2023 FY

# Our FOCUS

## Core ‘4’

Execute the B2B commercialisation of the geneType multi-risk test

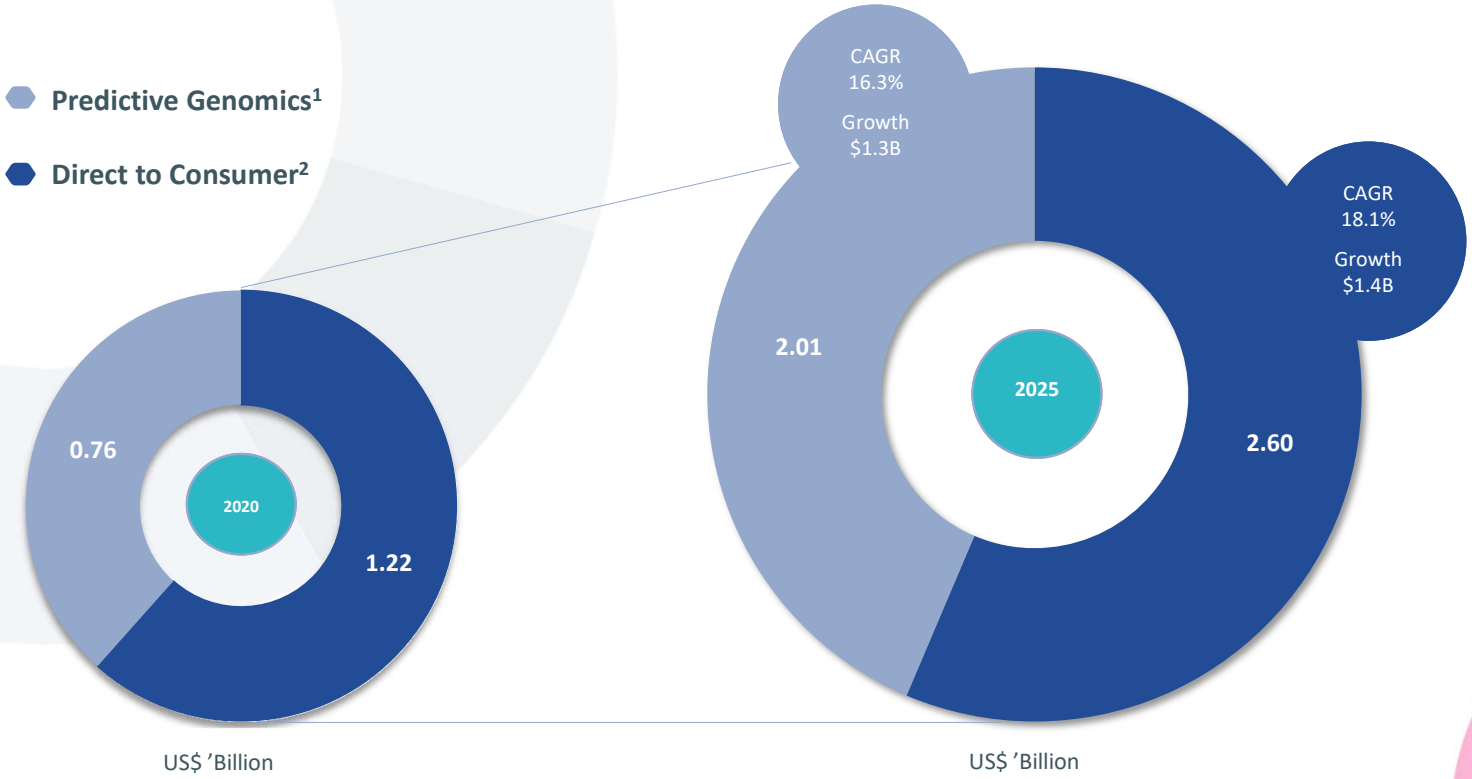
Demonstrate clinical validity & clinical utility of geneType tests

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




1. Newswire - 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[4] for the US payer

## Diseases Areas

**Oncology**

Breast Cancer
Colorectal Cancer
Prostate Cancer
Melanoma
Pancreatic Cancer
Ovarian Cancer

**Cardiovascular**

Atrial Fibrillation
Coronary Artery Disease

**Metabolic**

Type 2 Diabetes

Phase 1 Launch[2]

Phase 2 Launch[3]

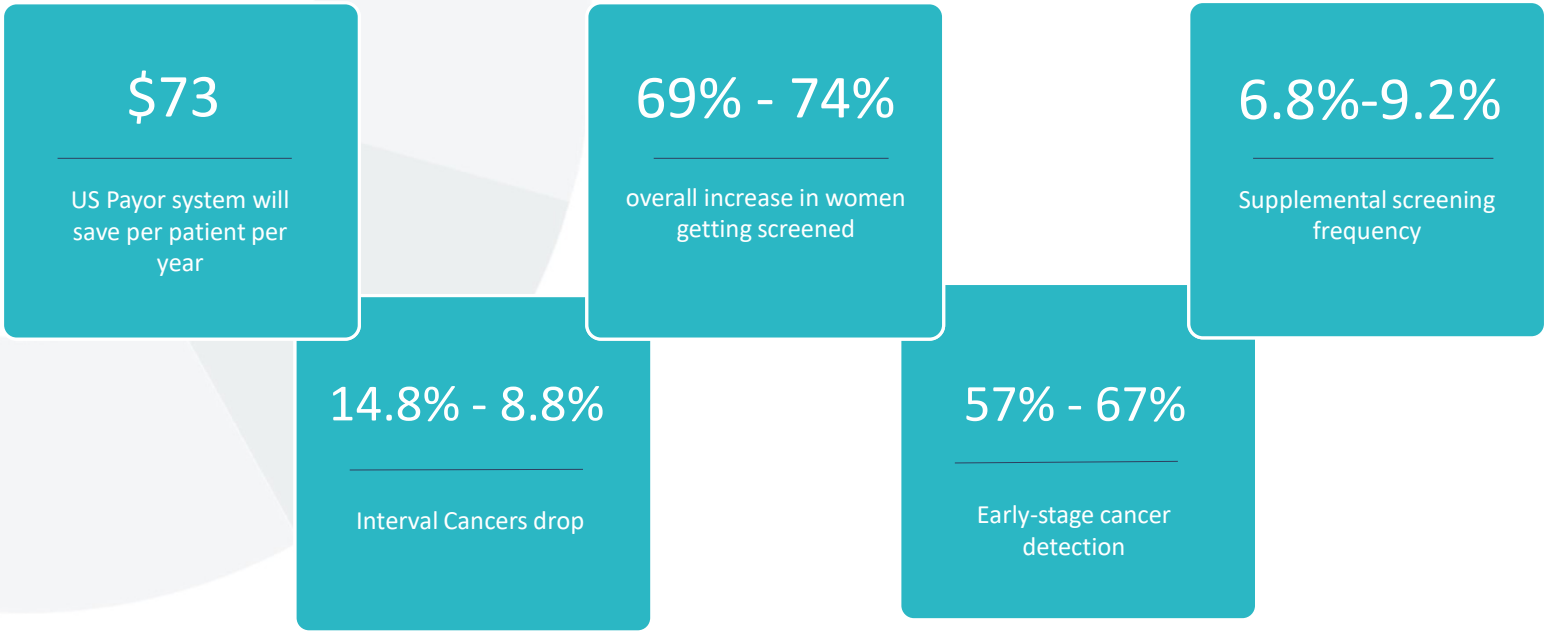
**GeneType Multi-test covers >70% of mortality & morbidity**


Guideline driven, Actionable results

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[1]

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



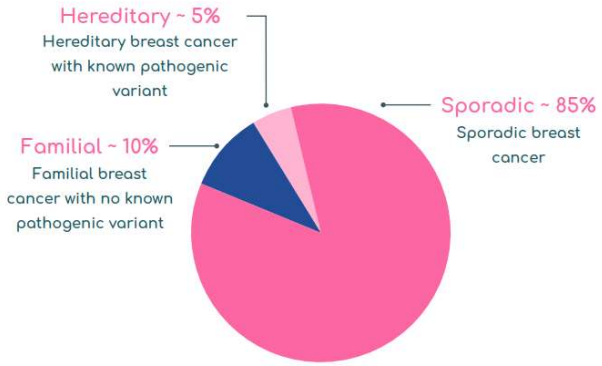

3.6% in annual savings to a payer system in the screening and treatment of breast cancer.

1 Corporates and Insurance market entry assessment - Health Economic Model completed by ALVA10 May 2022.

# GeneType Identifies up to **9** Times More Cancer Risk Patients Compared to Existing SoC Models[1]

DID YOU KNOW

The majority of breast cancer cases occur in women with no significant family history of the disease?




Many clinical risk assessment models exist (BCRAT or IBIS, for example), but when you need a clearer picture of risk, choose geneType.

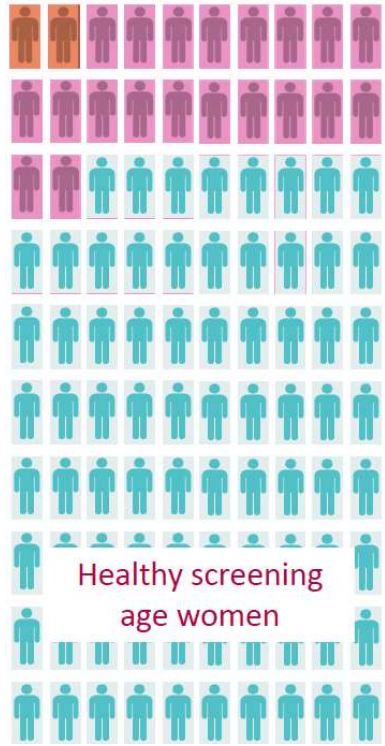
Proportion of women(40-69) with actionable risk (remaining lifetime risk scores >20%)

9x

geneType

IBISv7

| | IBISv7 | geneType |
|---|---|---|
| % cases >20% | 4.1% | 41.3% |
| % ER+ cases >20% | 3.9% | 42.9% |
| % ER− cases >20% | 2.8% | 35.8% |
| % stage 1 cases >20% | 4.7% | 42.3% |
| % stage 2+ cases >20% | 2.5% | 38.9% |
| % controls >20% | 2.5% | 22.4% |




The paper, titled *"Integrating Personalised Medicine into Preventative Care through Risk Stratification" Published in the Journal of Precision Medicine*

[1] https://www.thejournalofprecisionmedicine.com/wp-content/uploads/integrating-personalized-medicine-preventive-care.pdf

# Divisions of Operations

Existing divisions

Emerging divisions

**Oncology**
BC, CRC, PC, Melanoma

**CVD**
(Heart Disease)
IHD, AF

**COVID-19**
Serious disease risk (SDR)

**Metabolic diseases**
Diabetes

**Pharmoco-Genetics & Taliaz**
Companion diagnostics

**Germline testing**
BRCA, Lynch Syndrome and Somatic testing

**Carrier Testing**
NIPT & Reproductive carrier screening

**Lifestyle**
Ancestry and Microbiome
EasyDNA

geneType
Genetics for Life

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

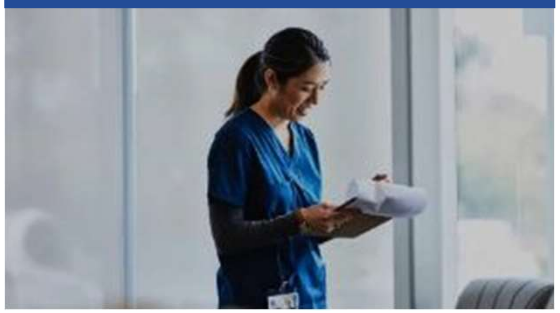

NEW Universal sample collection kit with TGA, FDA and EU regulatory approval[1]

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)



geneType

Oncology – GTG
Cardiovascular
Prenatal NIPT
Carrier testing
Clinical & Molecular
Metabolic

## Consumer initiated testing (CIT)

with medical supervision

geneType

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

AffinityDNA

Animal
Drug testing
Relationship
DNA Storage

# Pathways to Market – highest priority

## Medical & Payer Business to Business (B2B)

**Revenue Drivers**

Health Economic modeling completed by ALVA10*

Certifying reimbursable testing platform:
BRCA test & LYNCH Syndrome test

**Partners**

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

**Products**

geneType Multi-test

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

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
- 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.

# Collaborations

## Professor Bernard Rosner

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

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

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

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

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 Sloane Kettering Cancer

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

## Ohio State University

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

# 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

# Snapshot and Achievements last 12 months

## GeneType commercialization

- ✓ Phase 1 commercial release of the geneType Multi-Risk test in US
- ✓ >50 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

## 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

## 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

## 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

## Clinical Validity and IP Strategy

- ✓ 10 Patents granted
- ✓ 5 new provisional patents filed
- ✓ 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

# Thank you

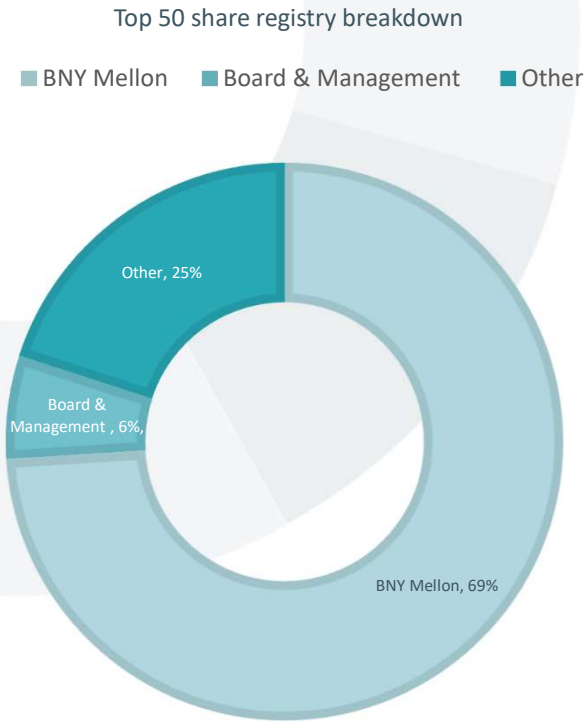
**Investor Relations**
**Adrian Mulcahy**
**Market Eye – Automic Group**
**M: +61 438 630 422**
**E: adrian.mulcahy@automicgroup.com.au**

www.linkedin.com/company/genetype-limited

www.genetype.com

# Appendices

# Corporate Overview




## Dual Listed on the ASX and Nasdaq

| **Financial Information** | |
|---|---|
| Share price (AUD) as at 25 October 2022 | 0.3c |
| ADR price (USD) as at 25 October 2022 | $1.20 |
| Ord Shares on Issue (M) | 9,234 |
| ASX 52-week trading (AUD low/high) | 0.3/0.8c |
| Nasdaq 52-week trading (USD low/high) | 0.95/3.04 |
| **Market Cap (A$M/US$M)** | **32.31/18.47** |
| Cash at 30 September 2022 | A$7.9m |
| Cash at 30 June 2022 | A$11.7m |
| Debt (30 June 2022 and 30 September 2022) | nil |

# Financial Overview

- **Net cash outflow of A$3.4 million in Q1 FY'23 (compared to Q4 FY'22 inflow of: A$197k) as we continue to grow EasyDNA and Affinity DNA brand sales and develop and commercialize our geneType tests**

- **Cash reserves of A$7.9 million at 30 September 2022 will be directed to:**
  - Drive 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 | 30-Sep-22 | 30-Jun-22 | Change |
|---|---|---|---|
| Net operating cashflow | (3,410) | 197 | -1831% |
| Receipts from customers | 2,056 | 2,013 | 2% |
| Research and Development and Staff costs | (2,126) | (1,429) | 49% |
| Cash | 7,495 | 11,733 | -32% |

[1] Based on cashflow projections

# Board and Management:
# Sales and Scientific expertise leading GTG

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

**Simon Morriss**
GAICD
Chief Executive Officer

**Richard Allman**
BSc, PhD
Scientific Advisor

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

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

**Mike Tonroe**
BSc, FCA, MAICD
Company Secretary

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

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

**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.

# 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