

# ASX Market Announcement

## Biotech Investors Luncheon – Emerging Biotech Conquering Global Markets

**Melbourne, Australia, 16 May 2022:** Genetic Technologies Limited (**ASX: GTG; NASDAQ: GENE**), Medlab Clinical Ltd (**ASX: MDC**) and Recce Pharmaceuticals (**ASX: RCE**) are pleased to be joining forces to present at the inaugural “Biotech Investors’ Luncheon”, held at the Sofitel Wentworth in Sydney 12.30pm on Monday 16 May 2022.

The luncheon is proudly sponsored by Blue Ocean Equities and Davies Collison Cave Lawyers.

Together, we are demystifying biotechnology investing, broadening access to major advancements that are gaining traction around the world and allowing investors to participate in market gains.

### About the event:

Australian biotechnology companies are increasingly offering technology that shows promise via the clinical and non-clinical trial path.

This creates attraction to established pharmaceutical companies. But a common problem is that some biotechs struggle to get the message across to investors and shareholders.

The lunch is designed to allow investors to become more knowledgeable in the role of biotech work happening in Australia, and the potential to change global ecosystems by looking at biotech from its core and getting a better understanding.

A copy of the Genetic Technologies presentation on the day can be found attached.

Authorised for release to ASX by the Board of Genetic Technologies Limited.

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### About Genetic Technologies Limited

Genetics Technologies Ltd is an established Australian-based molecular diagnostics company, specialising in the development of integrated genetic risk testing. Through its revolutionary proprietary technology, GeneType predicts an individual’s risk of developing chronic disease and enables physicians to proactively manage patient health. For more information, please visit [www.genetype.com](http://www.genetype.com).

### About Medlab Clinical

Medlab Clinical Ltd is an Australian biotechnology company, developing therapeutics using its proprietary delivery platform NanoCelle®. Its most advanced program is in cancer pain management with lead drug candidate NanaBis™, a medical cannabis product for cancer-related bone pain. For more information, please visit [www.medlab.co](http://www.medlab.co).

Medlab – *better medicines, better patient care*

### About Recce Pharmaceuticals

Recce Pharmaceuticals is pioneering the development and commercialisation of a New Class of Synthetic Anti-Infectives designed to address the urgent global health threat posed by antibiotic-resistant superbugs and emerging viral pathogens. For more information, please visit [www.recce.com.au](http://www.recce.com.au)

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# Introduction to GeneType Biotech Investors Luncheon

May 16, 2022

Authorised by the Board of Directors of Genetic Technologies Limited

ASX: GTG  
NASDAQ: GENE

# Notice: Forward looking statements

The purpose of the presentation is to provide an update of the business of Genetic Technologies Limited (the Company) ACN: 009 212 328 (ASX:GTG; NASDAQ:GENE). These slides have been prepared as a presentation aid only and the information they contain may require further explanation and/or clarification. Accordingly, these slides and the information they contain should be read in conjunction with past and future announcements made by the Company and should not be relied upon as an independent source of information. Please refer to the Company's website and/or the Company's filings to the ASX and SEC for further information.

The views expressed in this presentation contain information derived from publicly available sources that have not been independently verified. No representation or warranty is made as to the accuracy, completeness or reliability of the information. Any forward looking statements in this presentation have been prepared on the basis of a number of assumptions which may prove incorrect and the current intentions, plans, expectations and beliefs about future events are subject to risks, uncertainties and other factors, many of which are outside the Company's control. Important factors that could cause actual results to differ materially from assumptions or expectations expressed or implied in this presentation include known and unknown risks. Because actual results could differ materially to assumptions made and the Company's current intentions, plans, expectations and beliefs about the future, you are urged to view all forward looking statements contained in this presentation with caution.

This presentation should not be relied on as a recommendation or forecast by the Company. Nothing in this presentation should be construed as either an offer to sell or a solicitation of an offer to buy or sell shares in any jurisdiction.

# Our Overview

## Our Vision

Unlocking personalised preventative health

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## Our Global Presence

Expansion to over 40 countries

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## Our Market Opportunity

Go-to-market and growth pathways

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## Our Portfolio & Innovation

Cutting edge technology & 'game changing' partnerships

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## Our Channels & Divisions

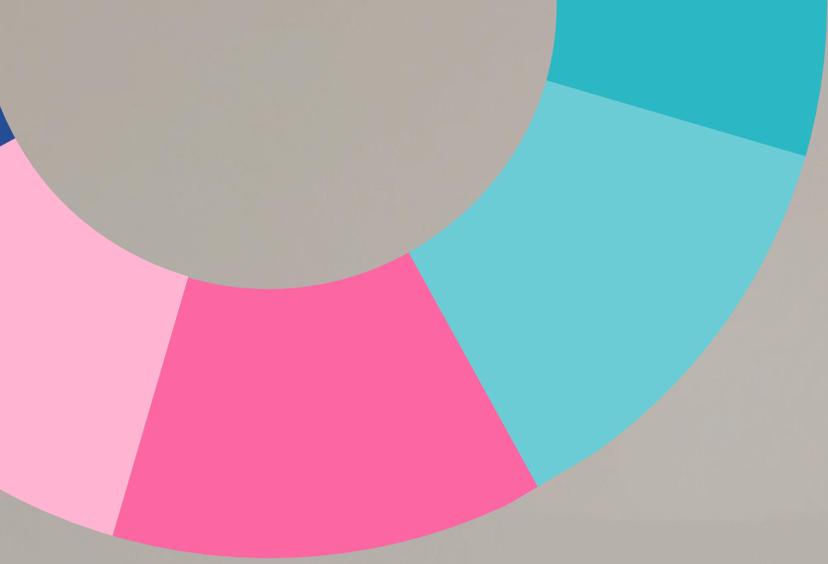
Segmentation and distribution channels

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## Key Operating Insights

Our focus Areas and brand performance

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# Genetype Vision



# Unlocking personalised preventative health

## Our Mission

Transform the conversation, transitioning from a one-size-fits-all model to personalised, predictive health assessment – where each person has the information, they need to manage their health according to their own risk.

Backed by over 20 years of experience, our doctors, scientist and technicians are translating genetic information into multi-tests that uniquely combine genetic and clinical risk models to predict risk of chronic diseases before onset.

Significant progress has been made in understanding the role of hereditary risk in chronic disease, however, many chronic conditions cannot be predicted by this risk alone.

Empowering physicians to improve health outcomes for people around the world. Tracking disease to its source and enabling a new era of personalised medicine.



# Patented integrated risk testing for a range of serious 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 are working to develop the next generation of integrated predictive genetic testing and assessment tools – empowering physicians and patients to proactively manage health.

- ✓ **8 Patents granted in the US**
- ✓ **5 Patents granted in China**
- ✓ **5 Patents granted in Hong Kong**
- ✓ **9 Patent families pending**

genetype's Polygenic Risk Scores (PRS) platform is a proprietary risk stratification platform delivering actionable outcomes from physicians and individuals



# Our Global Presence



54

Employees  
globally

40

Countries

27

Patents  
Granted  
(9 Pending)

14

Test  
Categories

51

Tests

12

Partner  
Laboratories

# Key Geographies and Collaborators

Genetype and EasyDNA Established in 40 countries with 12 established partnerships

## United States

geneType® Polygenic Risk Score (PRS) tests for breast, colorectal cancer and COVID-19 Risk Test available through CLIA Certified "High Complexity" Laboratories.

Genetype MultiTest<sup>3</sup> approved for Commercial Release by CMS<sup>2</sup> Feb 2022

## Europe & UK

EasyDNA available in multiple EU countries and UK

Commencing CE certification enabling EU launch of geneType MultiTest and other Novel genetic risk test in CY2022

## Asia

(Inc. SEA, China and India)

EasyDNA available in multiple countries across SEA

Commencing a scoping and Prioritising a market entry strategy into Asia

## Australia & New Zealand

Certification by Australian regulators NATA, to sell into the Australian market

Genetype MultiTest<sup>3</sup> approved for Commercial Release by NATA<sup>1</sup> Feb 2022

Our Melbourne owned Laboratory is NATA and CLIA certified



<sup>1</sup> National Association of Testing Authorities, Australia

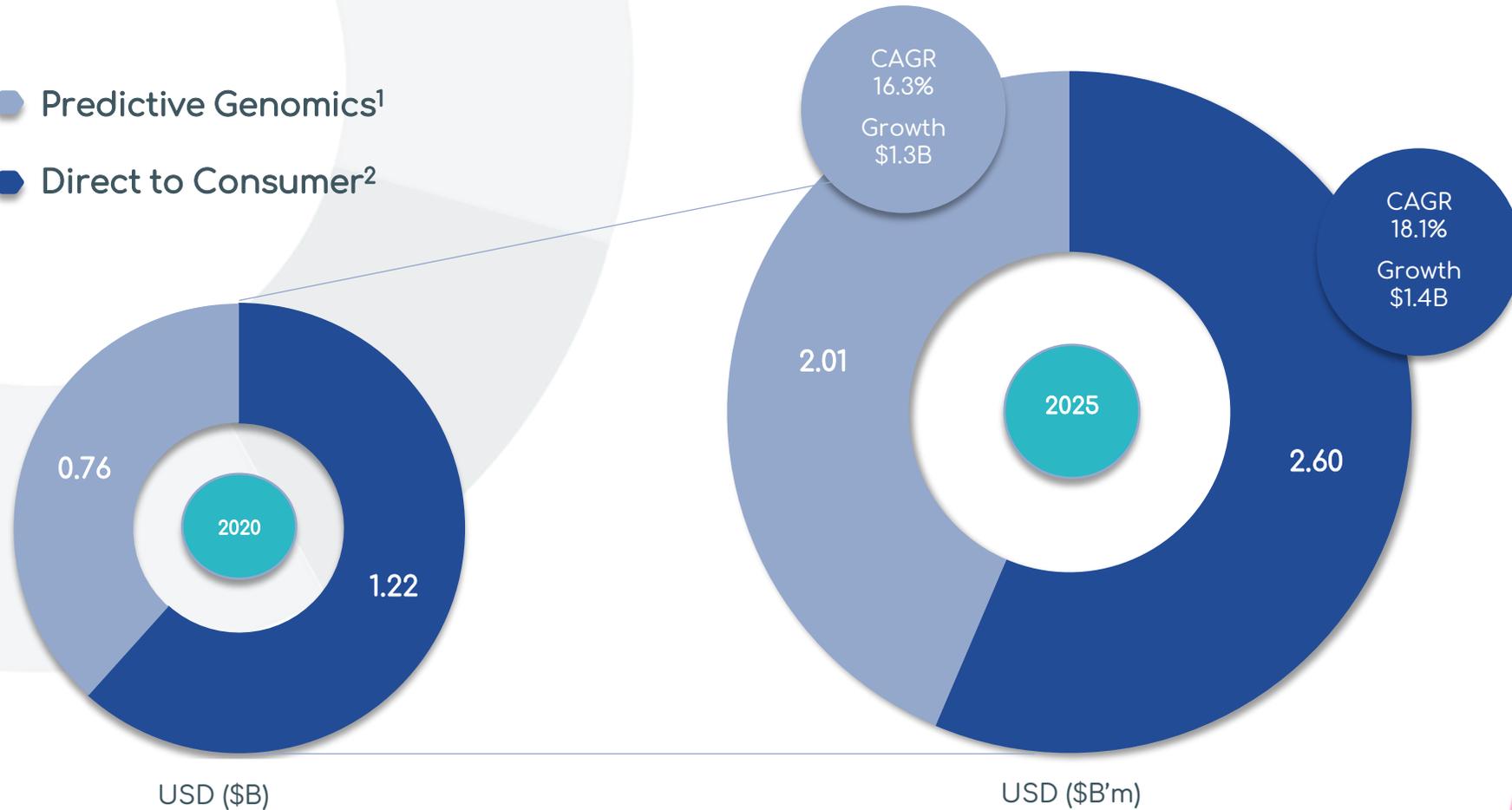
<sup>2</sup> Centers for Medicare & Medicaid Services

<sup>3</sup> GeneType for MultiTest includes Breast, Ovarian, Prostate & colorectal cancers plus Coronary artery disease and Type 2

# Our Market Opportunity

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

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



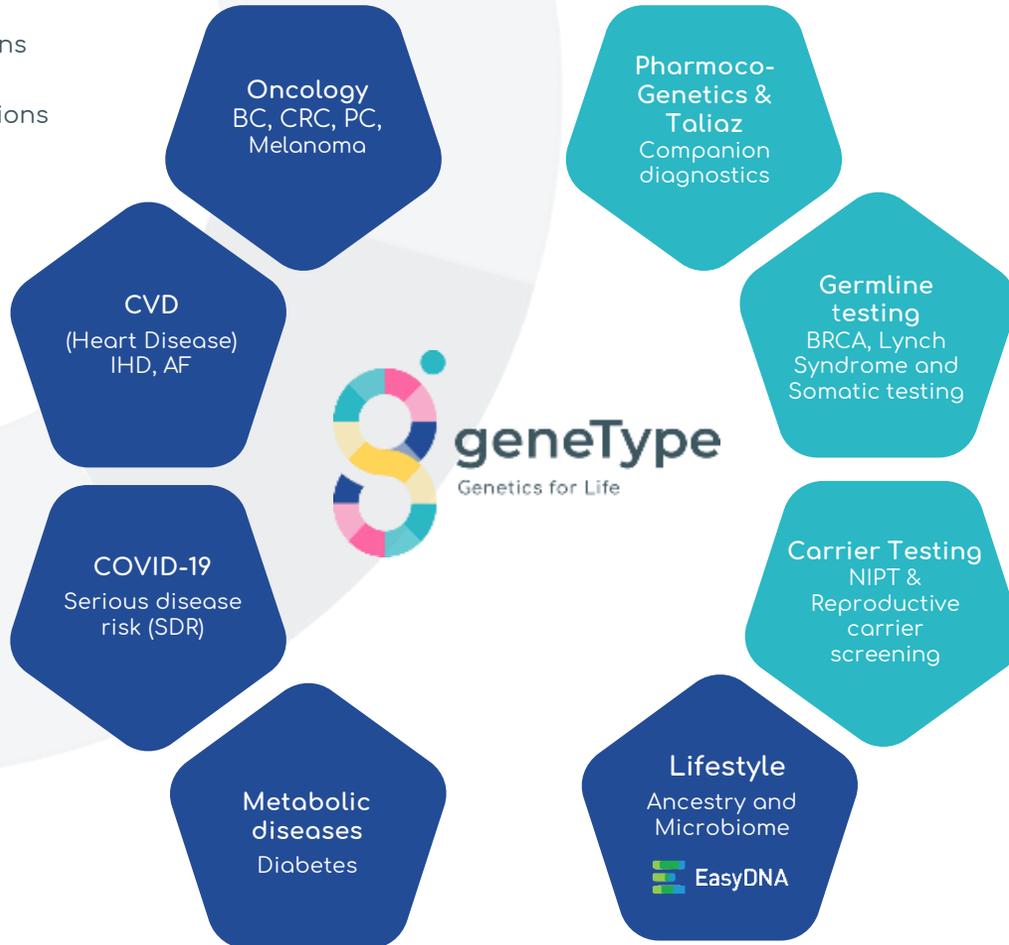
1. Newsire - Predictive Genetics Market Research Report by Type, by Demographics, by Test Type January 6 2022  
 2. Technavio Market Research reports - Direct-To-Consumer Genetic Testing Market by Distribution Channel, Service, and Geography - Forecast and Analysis 2021-2025

# Our Innovation Product Overview



# 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>

# Our latest Innovation – Multi- Risk Test

A companion diagnostic PRS to help identify risk of serious disease for up to 70% of Mortalities and Morbidities and save payors

## Diseases Areas

### Oncology

Breast Cancer  
 Colorectal Cancer  
 Prostate Cancer  
 Melanoma  
 Pancreatic Cancer  
 Ovarian Cancer

### Cardiovascular

Atrial Fibrillation  
 Coronary Artery Disease

### Mental Health

Talioz<sup>4</sup>

### Metabolic

Type 2 Diabetes

 Phase 1 Launch <sup>2</sup>

 Phase 2 Launch <sup>3</sup>

GeneType Multi-test to include >70% of mortality & morbidity



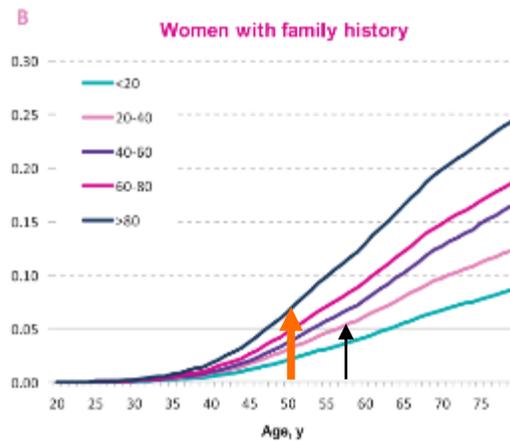
NEW Universal sample collection kit with TGA, FDA and EU regulatory approval<sup>1</sup>

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. Product in Markets under license

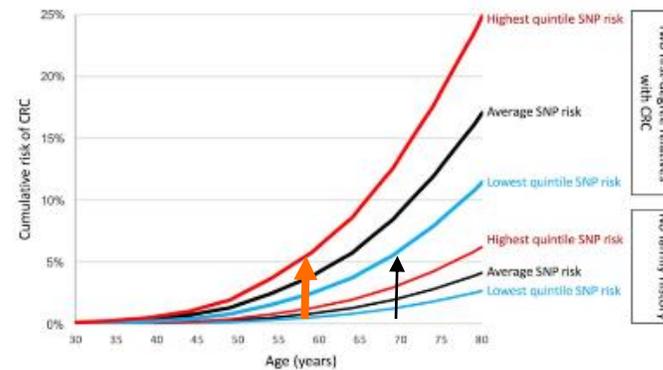
# Integrated personalised risk assessment

geneType integrates genetic risk and clinical risk to better stratify individual risk. Patients with potentially high risk may exceed actionable clinical guidelines 10 – 15 years earlier than those with low risk <sup>1,2,3</sup>

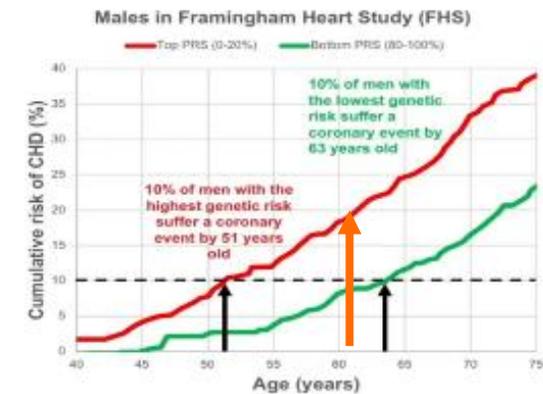
### Breast Cancer (BC)<sup>1</sup>



### Colorectal Cancer (CRC)<sup>2</sup>



### Chronic Heart Disease (CHD)<sup>3</sup>



↑ Low polygenic risk score      ↑ High polygenic risk score

geneType detects patients at an actionable risk of serious disease 10 – 15 years earlier than currently possible. Potentially significantly improving patient outcomes and health economics

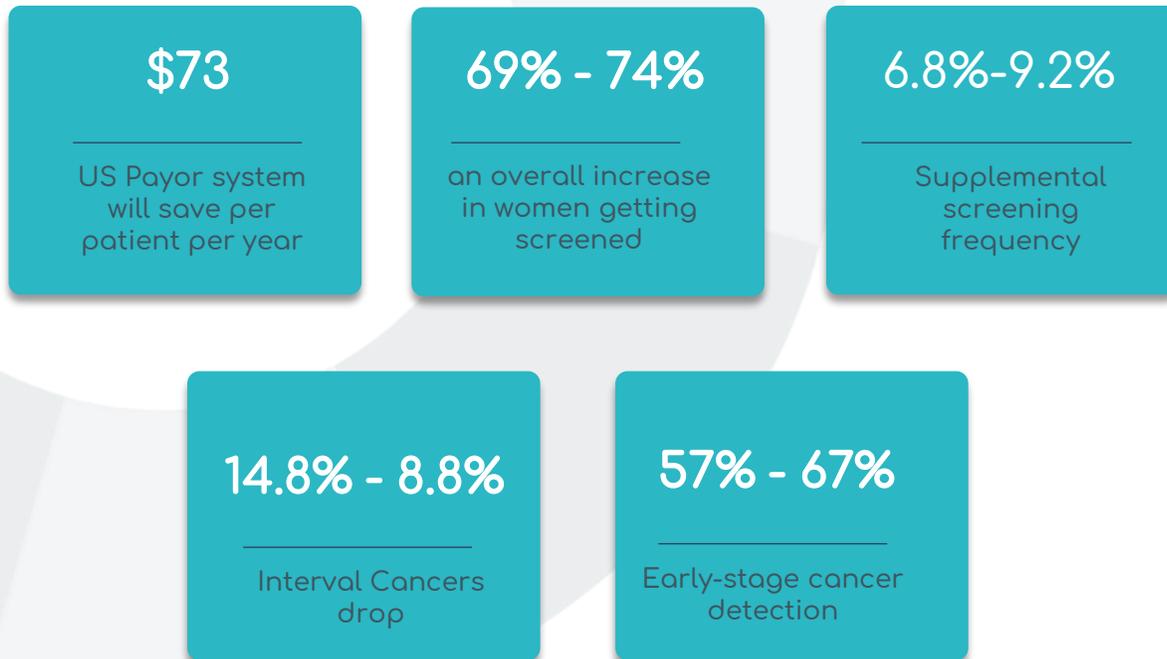
<sup>1</sup> Mavaddat et al. (2015) JNCI.

<sup>2</sup> Jenkins et al. (2019) Familial Cancer.

<sup>3</sup> Abraham et al. (2016) Eur Heart J.

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

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



Annual Payor Net Savings per Patient Tested  
Excludes Cost of GTG Test  
Treatment & Screening Costs Only



The payer system will be near breakeven in 2 years based on the cost. Each year, the payor will save an additional \$73 on average per patient tested.

# Pathways to Market

	Direct to Consumer Testing (DTC) with no medical supervision	Consumer initiated testing (CIT) with medical supervision	Medical Business to Business (B2B)
Revenue Drivers	Leveraging the EasyDNA Brand and Platform provides the foundation to grow in 40 countries	Building consumer Awareness of serious disease test via a platform that integrates medical supervision  Launched US and Australia CIT platforms in 2020	Health Economic modeling being completed by ALVA10*  Certifying reimbursable testing platform: BRCA test & LYNCH Syndrome test
Partners	Agreements with 12 laboratories in North America, AsiaPac and Europe	Medical partners: LimsABC InTeleLabs in the US Phenix Health in Australia	An plan curated for: Payers / Insurers* Primary Care Physicians, Specialists, Surgeons, Allied Health
Products	EasyDNA paternity, ancestry, gut microbiome testing and non-medical related genomic tests  	geneType for Breast Cancer geneType for Colorectal Cancer geneType Multi-test  	geneType Multi-test  BRCA test & LYNCH Syndrome test  

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

# Pathways to Market

## Executing a multi-brand strategy

**1** Direct to consumer



**easyDNA**

- Ancestry
- Paternity
- Health & Wellbeing
- Pharmacogenetics
- Animal
- Drug testing
- Relationship

**2** Consumer-initiated testing ± telehealth support



**geneType**

- Health & Wellbeing- Nutrition
- Oncology – MultiTest
- Cardiovascular – MultiTest
- Metabolic – MultiTest
- COVID Risk Test
- Pharmacogenomics

**3** Healthcare professional requested test



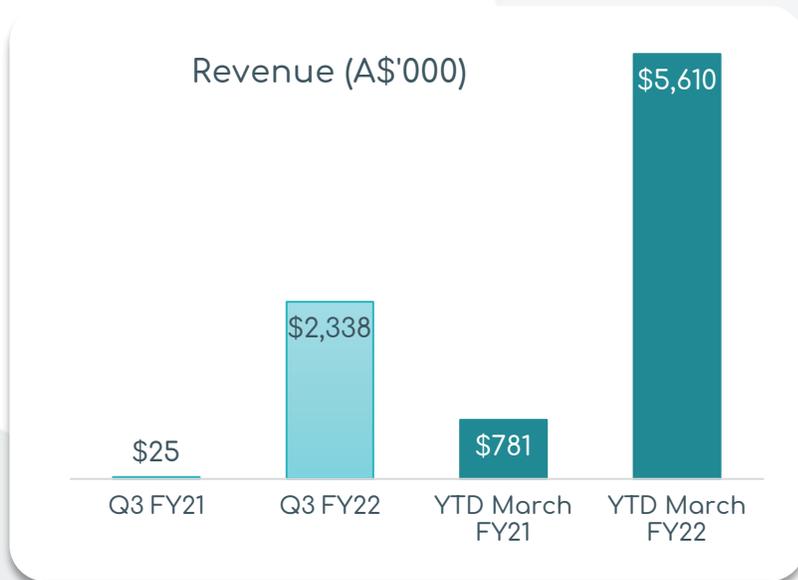
**geneType**

- Oncology – GTG
- Cardiovascular
- Prenatal
- Clinical & Molecular
- Metabolic
- Taliaz Predictix

\*availability upon regulatory approval

# Key Operating Insights

# Delivering Revenue and Growth YTD March FY22



REVENUE YTD  
AUD \$5.6m

CASH BALANCE  
AUD \$11.3m\*

GROSS MARGIN YTD  
AUD \$2.9m

GROSS MARGIN YTD  
52.1%

## Strategic & Operational Highlights

- YTD Growth of 475% in revenue vs last year
- EasyDNA performance showing versus the prior full period +15.2% in volume growth and +9.9% in revenue growth
- Received accreditation from NATA<sup>1</sup> and CMS<sup>2</sup> for the MultiTest on 17 February 2022 with commercial launch currently underway for Physicians
- US patent No. US 11,257,569 granted in 'Methods of assessing the risk of developing a severe response to Coronavirus infection'.
- A\$1.2 million in receivable R&D tax incentives (recognized as revenue), up by 124% on pcp, reflecting the continued focus on development in research on genomics-based technology

<sup>1</sup>National Association of Testing Authorities, Australia

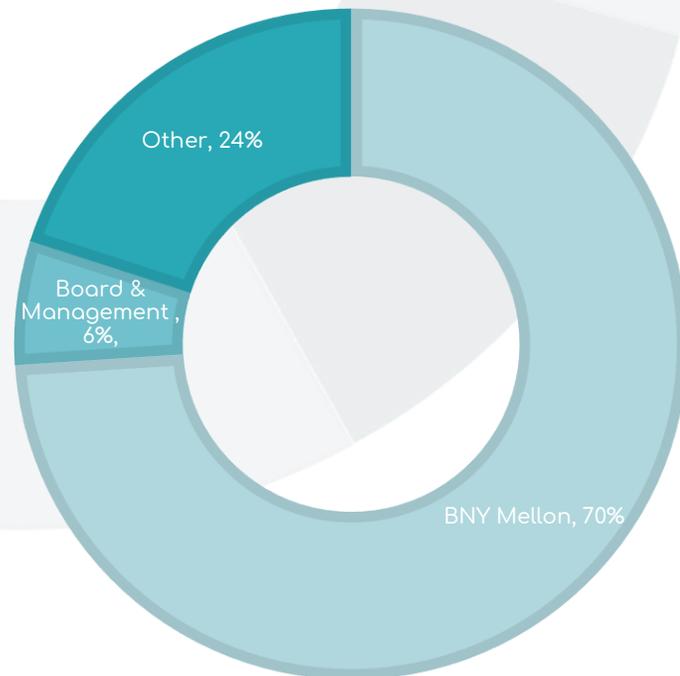
<sup>2</sup>Centers for Medicare & Medicaid Services

\*Cash Balance excluded AUD\$1.4m R&D Tax Incentive

# Corporate Overview

Top 50 share registry breakdown

■ BNY Mellon ■ Board & Management ■ Other



## Dual Listed on the ASX and Nasdaq

### Financial Information

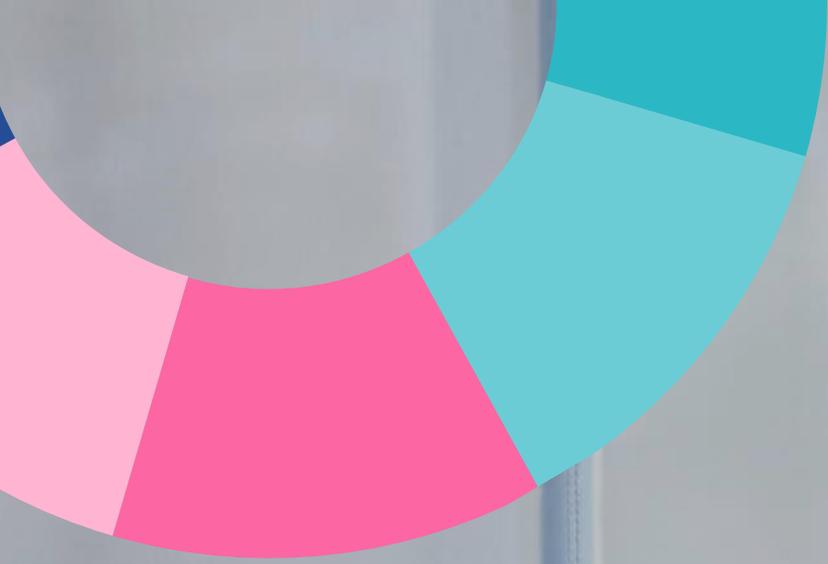
Share price (AUD) as at 19 April 2022	0.4c
ADR price (USD) as at 19 April 2022	\$1.85
Ord Shares on Issue (M)	9,234
ASX 52-week trading (AUD low/high)	0.4/1.2c
Nasdaq 52-week trading (USD low/high)	1.70/5.18
<b>Market Cap (A\$/US\$M)</b>	<b>36.94/28.16</b>
Cash at 31 March 2022	A\$11.4m
Cash at 31 December 2021	A\$13.5m
Debt (31 December 2021 and 31 March 2022)	nil

# Financial Overview

- Cash burn of A\$2.1 million in Q3 FY22 (compared to Q2 FY'22: A\$2.2 million) as we continue to grow EasyDNA brand sales and develop and commercialize our geneType tests
- Cash reserves of A\$11.4 million after EasyDNA acquisition costs of A\$3.5 million give 21 month<sup>1</sup> runway to:
  - Support the introduction and distribution of new geneType products in the United States and Europe
  - Develop the direct-to-consumer sales channel through EasyDNA
  - Reimbursement studies for the polygenic risk tests;
  - Introduction of germline testing division;
  - General product research and development; and
  - For general working capital and potential acquisitions.

A\$'000	31-Dec-21	31-Mar-22	Change
Net operating cashflow	(2,157)	(2,056)	-5%
Receipts from customers	1,809	1,967	9%
Research and Development and Staff costs	1,313	1,244	-5%
Cash	13,509	11,350	-16%

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

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# Summary



# Snapshot and Achievements

## Signed multi-year distribution agreement

- ✓ License and distribution agreement for COVID-19 Risk Test with IBX
- ✓ Expanded Covid risk test distribution with 1Health and Vitagene
- ✓ Launched tests on CIT in USA & AUS<sup>1</sup>

## New Multi-test pathway to launch

- ✓ New Multi-test technical validation complete and submitted to NATA and CMS for final regulatory approval
- ✓ Covering up to 70% of mortalities and morbidities

## Acquired revenue generating platform

- ✓ Showing solid Quarter on Quarter growth in volume and value
- ✓ A global platform to launch new geneType products<sup>3</sup>

## Robust patient portfolio & clinical credibility

- ✓ 17 patents granted
- ✓ 9 patent families pending
- ✓ Multiple peer-reviewed publications and;
- ✓ Collaborations with 5 prestigious academic and medical establishments

## Focused on R&D collaborations and Innovation

- ✓ African American Breast Cancer Research Collaboration with Professor Colditz at Washington State University
- ✓ 2021 San Antonio Breast Cancer Symposium
- ✓ American Academy of Anti-Aging Medicine (A4M)
- ✓ Nurses Health Study (NHS)

## Solid balance sheet

- ✓ A\$11.4million cash balance
- ✓ 21-month runway to drive execution<sup>2</sup>

<sup>1</sup> GeneType for Breast Cancer and Colorectal Cancer certified for sale via online sales platform.

<sup>2</sup> Runway based on current cash projections and including the acquisition of EasyDNA

<sup>3</sup> Subject to local regulatory requirement

# Our 6 Areas



Commercialisation of the geneType suite of multi-risk tests



EasyDNA Growth: New Test. New Channels. New Markets.



Demonstrate clinical validity & clinical utility of geneType tests



Bolster commercial bias to our OPEX



Talent & capability acquisition



Innovation: Gene Ventures

# Thank you

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# Appendices

# 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

## 8 Patents granted in the US

- Patent No: US 11,257,569, Methods of assessing risk of developing a severe response to Coronavirus infection
- Patent 11,031,098, Computer systems and methods for genomic analysis
- Patent 10,683,549, Methods for assessing risk of developing breast cancer
- Patent Nos. 9,051,617; 9,068,229 and 9,702,011 covering three of the core genetic markers included in the BREVAGenplus® risk assessment test
- Patent No. 7,127,355 offering broad protection re: methods of genetic analysis (the concept of combining clinical risk assessment with genetic risk factors to improve predictability over clinical risk assessment alone)
- Patent No. 6,969,589 covering the identification of informative SNPs

## 5 Patents granted in China

- Patent Nos. 200680051710.0; 201310524782.4; 201310524916.2 and 201310524765.0 “Markers for Breast Cancer”
- Patent No. 201080033130.5 Methods for Breast Cancer Risk Assessment

## 5 Patents granted in Hong Kong

- Patent Nos. 09101235.4; 12112875.1; 12112368.5 and 12112874.2 “Markers for Breast Cancer”
- Patent No. 12109000.5 Methods for Breast Cancer Risk Assessment

## 9 Patent families pending

- Methods for breast cancer risk assessment
- Methods for assessing risk of developing breast cancer
- Improved methods for assessing risk of developing breast cancer
- Markers for breast cancer
- Methods for genetic analysis
- Methods for genomic analysis
- Methods for assessing risk of developing colorectal cancer
- Methods of assessing risk developing a disease
- Methods for assessing risk of developing a severe response to coronavirus infection

# 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 &  
Chief Medical Officer



**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

# 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