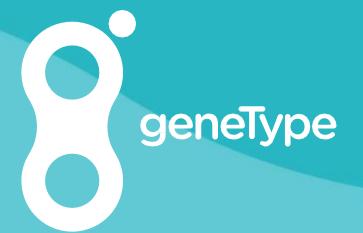
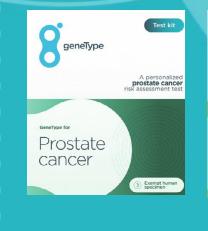
# Genetic Technologies



Genetic based preventative health platform

NASDAQ: GENE
HC Wainwright & Co
BioConnect 2021 Conference
11-14 January 2021







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# Notice: Forward looking statements



The purpose of the presentation is to provide an update of the business of Genetic Technologies Limited ACN: 009 212328 (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 Genetic Technologies 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.

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# Genetic Technologies - Leader in Genomics



# Strong focus on R&D

Over a decade of R&D on the development of polygenic risk scores

# 20 staff across Australia and US

Scientific leadership under Dr Richard Allman
– a pioneer in the development of polygenic
risk scores

## Robust patent portfolio

15 patents granted and 7 patent families pending

# \$18 million

Strong cash balance with 18-24 month runway<sup>1</sup>

# Publications and academic collaborations

Two peer-reviewed publications and four collaborations with prestigious academic and medical establishments

### **Up to 70%**

Coverage from tests in development for serious disease case including major oncological, metabolic and degenerative diseases









We aim to offer the most comprehensive suite of polygenic risk assessment tests on the market

# **Product Overview**



#### Released 2019/2020

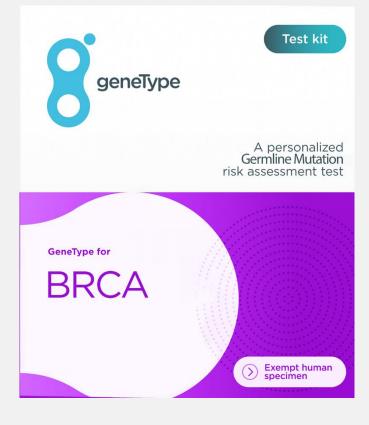




Colorectal Cancer

**Breast Cancer** 

#### **Germline Products Under Development**

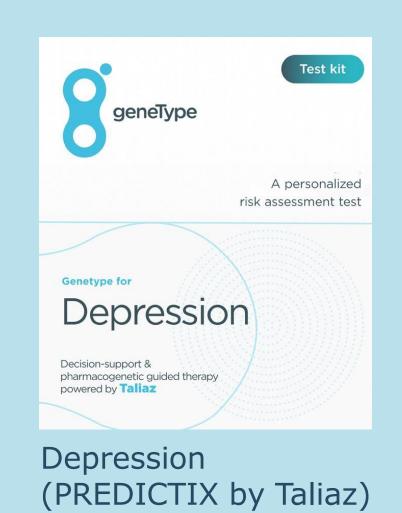






Lynch Syndrome

# COVID-19 SDR [serious disease risk] Exempt human specimen COVID-19



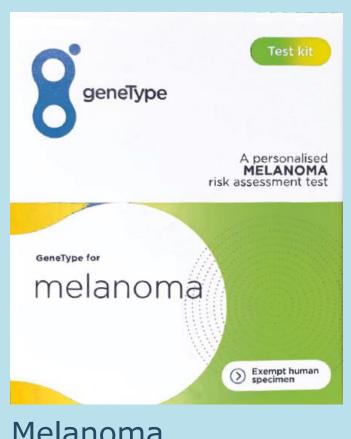




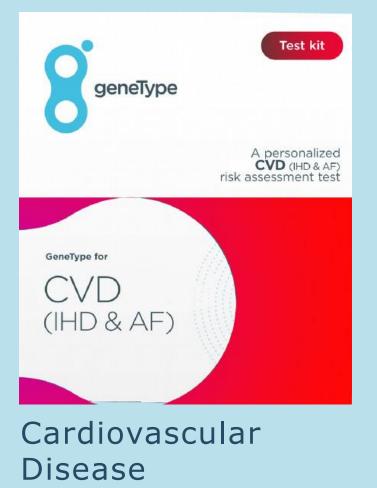


**Prostate Cancer** 

**PRS Products Under Development** 



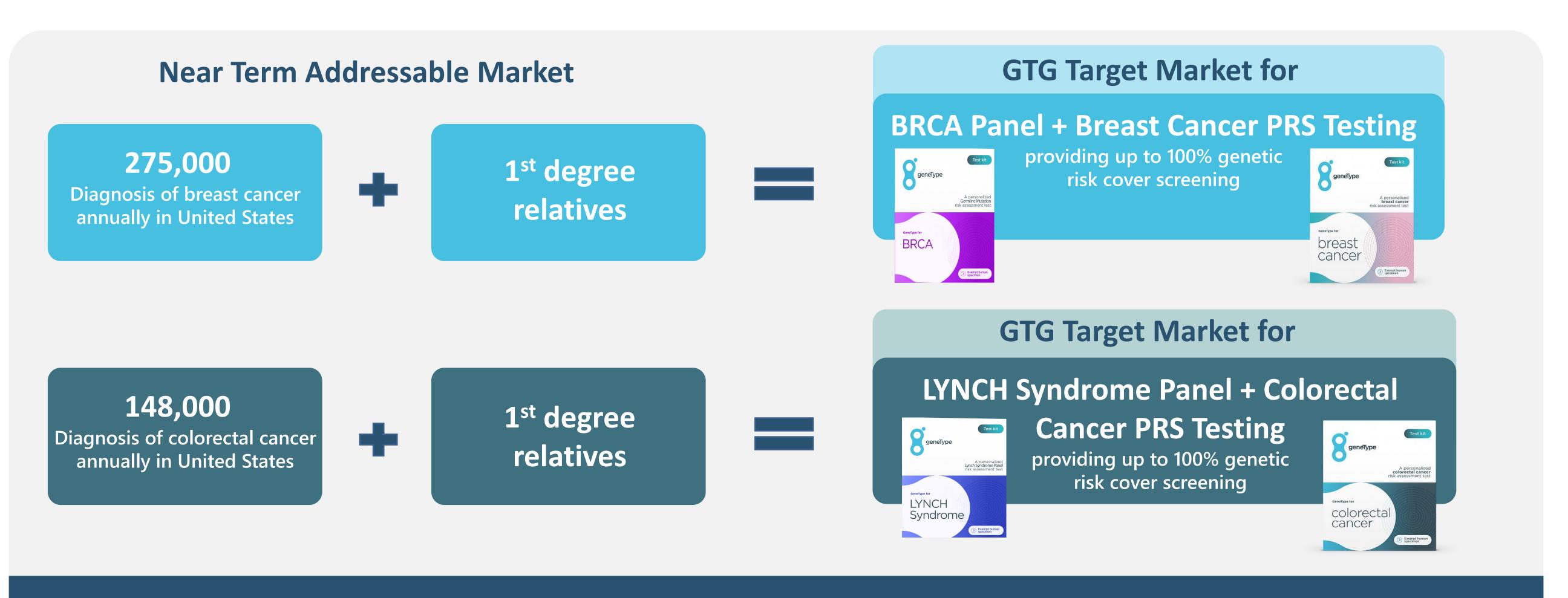
Melanoma



# Significant market opportunity GTG aims to provide predictive pre-symptomatic test



GTG aims to provide predictive, pre-symptomatic testing to inform lifestyle choices and healthcare discussions



Global Predictive Genetic Testing Market anticipated to exceed \$28bn by 20261

<sup>1.</sup> Genetic Testing Market Size By Test Type (Predictive Testing, Carrier Testing, Prenatal and New-born Testing, Diagnostic Testing, Pharmacogenomic Testing, Nutrigenomic Testing), By Application (Cancer, Genetic Disease, Cardiovascular Disease), Industry Analysis Report, Regional Outlook, Application Potential, Competitive Market Share & Forecast, 2020 – 2026; Published Date: Feb 2020; Authors: Sumant Ugalmugle, Rupali Swain

<sup>2.</sup> PRS = Polygenic Risk Score

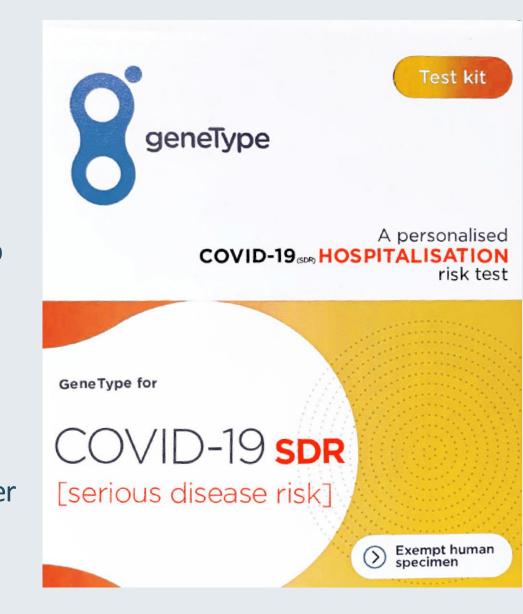
# Responding to unique opportunities and challenges



Genetype for COVID-19 SDR Test - World first genetic risk test that predicts your risk of hospitalisation & life threatening complications

#### Highlights

- Rapid response and creation of the test
  - Expected to be market ready Q1 CY21<sup>1</sup>
- Distribution opportunities via license agreement with major labs<sup>2</sup>
  - In discussion with major north American labs that are able to scale up and offer significant efficiencies that translate into:
    - faster distribution timeframes via existing distribution networks
    - reduced cost of implementation with existing marketing platforms
    - tests can be provided at significantly lower cost than GTG could offer
- Has the potential to be an alternative to a one size fits all lockdown strategy
- Currently undergoing technical validation in GTG's laboratory



#### **Product Overview**

- Simple oral swab test
- Allows for remote screening
- Accurate and low cost<sup>3</sup>
- Designed to identify who:
  - may be at risk of serious life-threatening complications
  - should isolate as a precaution
  - should be prioritised for vaccination
- Combines genetic risk with clinical risk
- Could assist with management of individuals who are not suitable or have serious reservations with regards to immunisation
- Could provide the ability to prioritise medical intervention for high-risk individuals
- Over 100% better at identifying risk than age and gender alone<sup>3</sup>
- 1. Increased data set is currently undergoing integration into our risk test. Product launch expected to be extended by 4 weeks.
- 2. GTG anticipates the registration of an LDT COVID-19 severity test should take less than 45 days after validation (based on estimates received)
- 3. "An integrated clinical and genetic model for predicting risk of severe COVID-19" available at: https://www.medrxiv.org/content/10.1101/2020.09.30.20204453v1.full.pdf

# Parti Genetype

# Partnership to provide expanded product offering



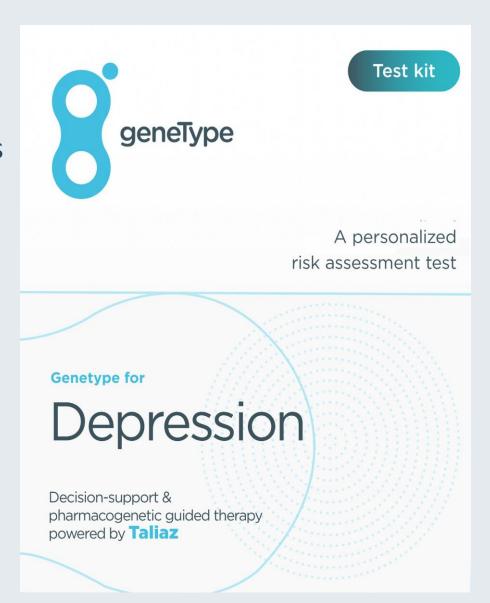
Genetype for Depression - Powered by Taliaz's PREDICTIX platform

#### Highlights

- Key opportunity with strong product alignment to integrate into our platform in line with our mandate to expand our product offering
  - Provides entry into mental health and pharmacogenomics segments
- Regulatory status:
  - CE Marked
  - In the process of acquiring TGA approval, expected to be market ready by the end of 1H CY21
- Anticipated for market release in 2H CY21
- Distribution Agreement
  - Minimum distribution of 8,000 tests over the initial three-year term
  - Pricing not yet determined but expected to be in line with current test pricing of ~A\$350 per test

1 in 8

Australian prescribed antidepressants annually<sup>1</sup>



#### **Product Overview**

- Utilising a combination of:
  - Genetic, metabolic, clinical and demographic background data; in conjunction with
  - Artificial Intelligence and Machine Learning
- Creates diagnostic and pharmacogenetic solutions that are
   47% better than current best in class practices.
- Better individual outcomes due to superior therapeutic drug selection

47%

Improvement on accuracy of prescribing antidepressant<sup>2</sup>

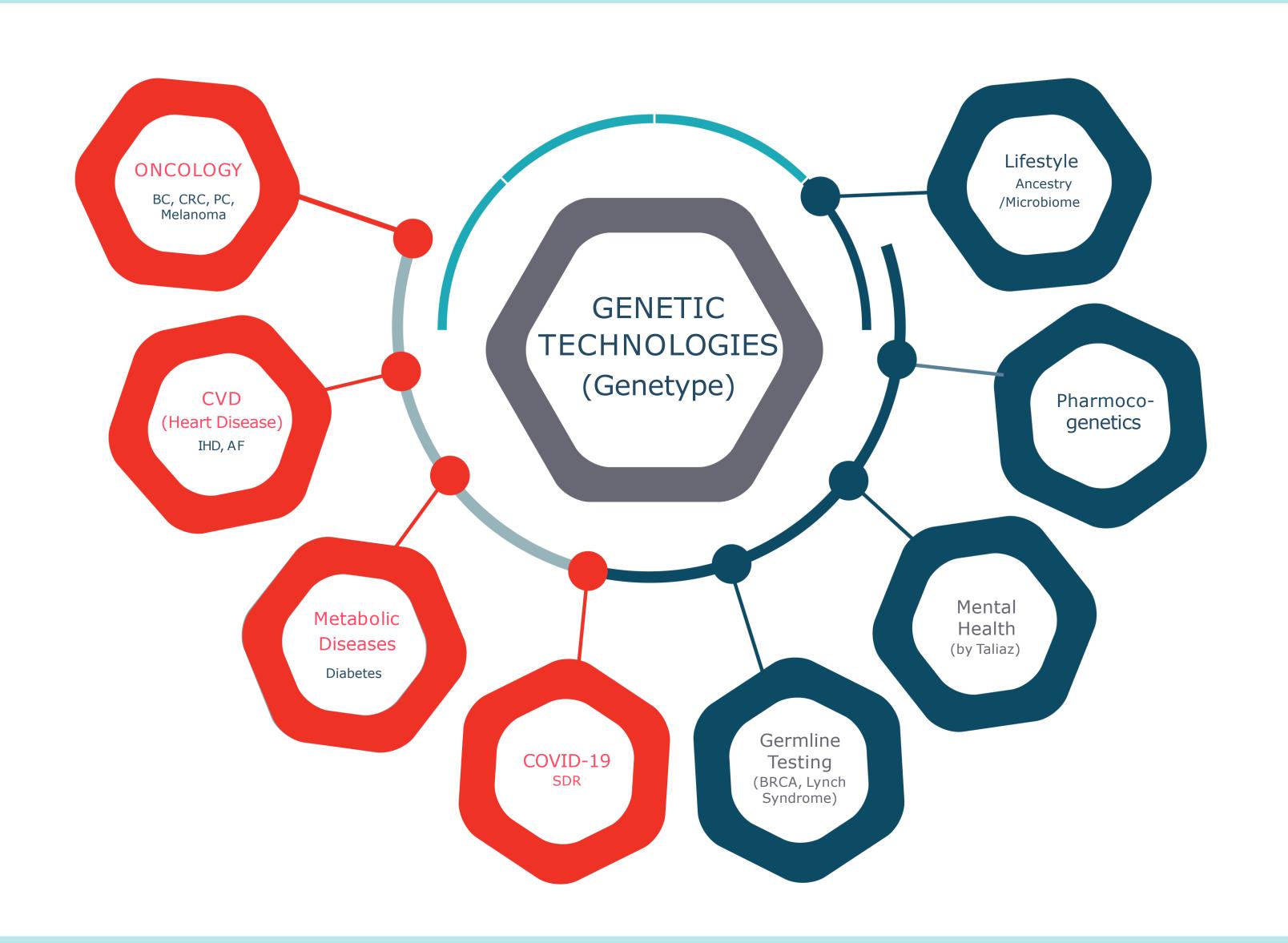
1 in 10

Americans prescribed antidepressants annually<sup>3</sup>

- 1. Source: Psychwatchaustralia
- 2. Based on a retrospective analysis of STAR\*D study medications versus current clinician treatment selection prescribing accuracy (Chekroud et al., 2016). STAR\*D is one of the world's largest prospective studies for optimal antidepressant administration.
- 3. Source: https://www.health.harvard.edu/blog/astounding-increase-in-antidepressant-use-by-americans-201110203624

# Expanding divisions and product offerings





# **Regional Distribution**





#### **United States**

- Certification by US regulators CLIA to sell into the USA
- One product<sup>1</sup> currently certified with further products expected to be submitted in next 12 months



#### **Australia**

- Certification by Australian regulators **NATA**, to sell into the Australian market
- Two products<sup>2</sup> currently certified and further products expected to be submitted in next 12 months



#### Europe

• Looking to commence CE certification with the view of entering the European market with our novel genetic risk tests in CY2021

- 1. GeneType for Breast Cancer certified for sale via online sales platform
- 2. GeneType for Breast Cancer and Colorectal Cancer certified for sale via online sales platform

# Sales platforms and methods

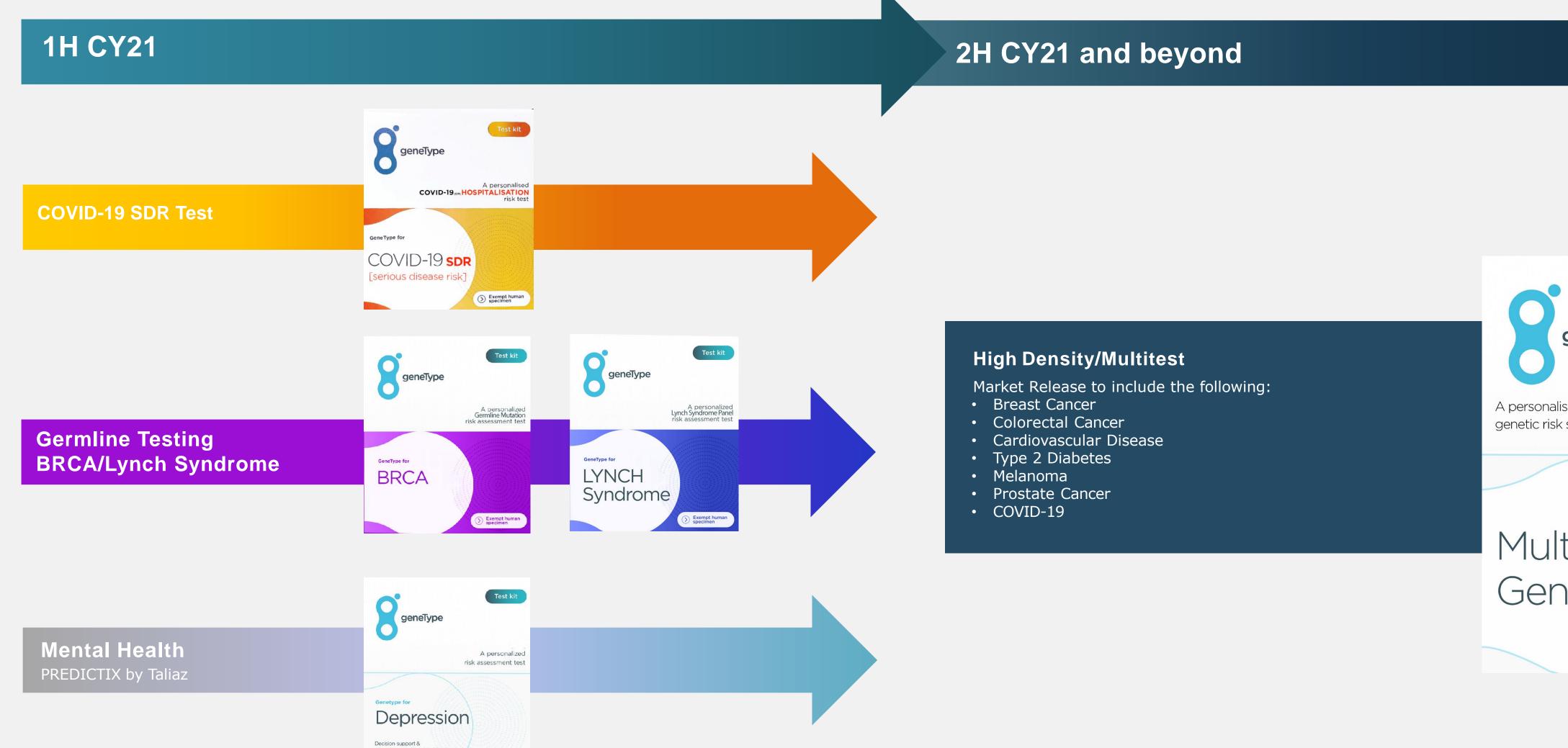


#### • Third Party Licensing

- Provides enhanced distribution and product offering via:
  - Licensing of own products for enhanced distribution opportunities (ie. COVID-19 distribution opportunities with US labs)
  - Licensing of novel products for enhanced product offering (ie. PREDICTIX by Taliaz)
- Consumer initiated testing (CIT) with medical supervision
  - Launched US and Australia CIT platforms in 2020 with medical supervision undertaken by InTeleLabs in the US and Phenix Health in Australia
  - Current products include GeneType for Breast Cancer and Genetype for Colorectal Cancer priced at AUD\$349 per test
- Direct to consumer testing (DTC) with no medical supervision
  - Will be leveraged for ancestry and gut microbiome testing
  - Scheduled for development following the establishment of the regulated disease and reimbursable segments
- Business to business sales via the medical profession
  - Adversely impacted by COVID-19 restrictions but remains a key avenue for education and sales
  - Combined with an educational program to target health professionals mediated VR professional industry education content providers
- Reimbursement
  - Certifying reimbursible Germline testing platform anticipated to be completed by end of 1H CY2021
    - BRCA test: Medicare Benefits Schedule:
      - Item 73296 Fee: \$1,200.00 Benefit: 75% = \$900.00 85% = \$1,115.30<sup>1</sup>
      - Item 73297 Fee: \$400.00 Benefit: 75% = \$300.00 85% = \$340.00<sup>2</sup>
    - LYNCH Syndrome test: Medicare Benefits Schedule
      - Item 73354 Fee: \$1,200.00 Benefit:  $75\% = $900.00 85\% = $1,115.30^3$
- 1. http://www9.health.gov.au/mbs/fullDisplay.cfm?type=item&q=73296&qt=ItemID
- 2. http://www9.health.gov.au/mbs/fullDisplay.cfm?type=item&q=73297&qt=ItemID
- 3. http://www9.health.gov.au/mbs/fullDisplay.cfm?type=item&q=73354&qt=item&criteria=lynch%20syndrome

# Outlook





Multitest by Genetype

Oncological Cardiovascular Metabolic Test Kit

Test kit

# Strategy



#### • GTG have now established a clear product pipeline and direction:

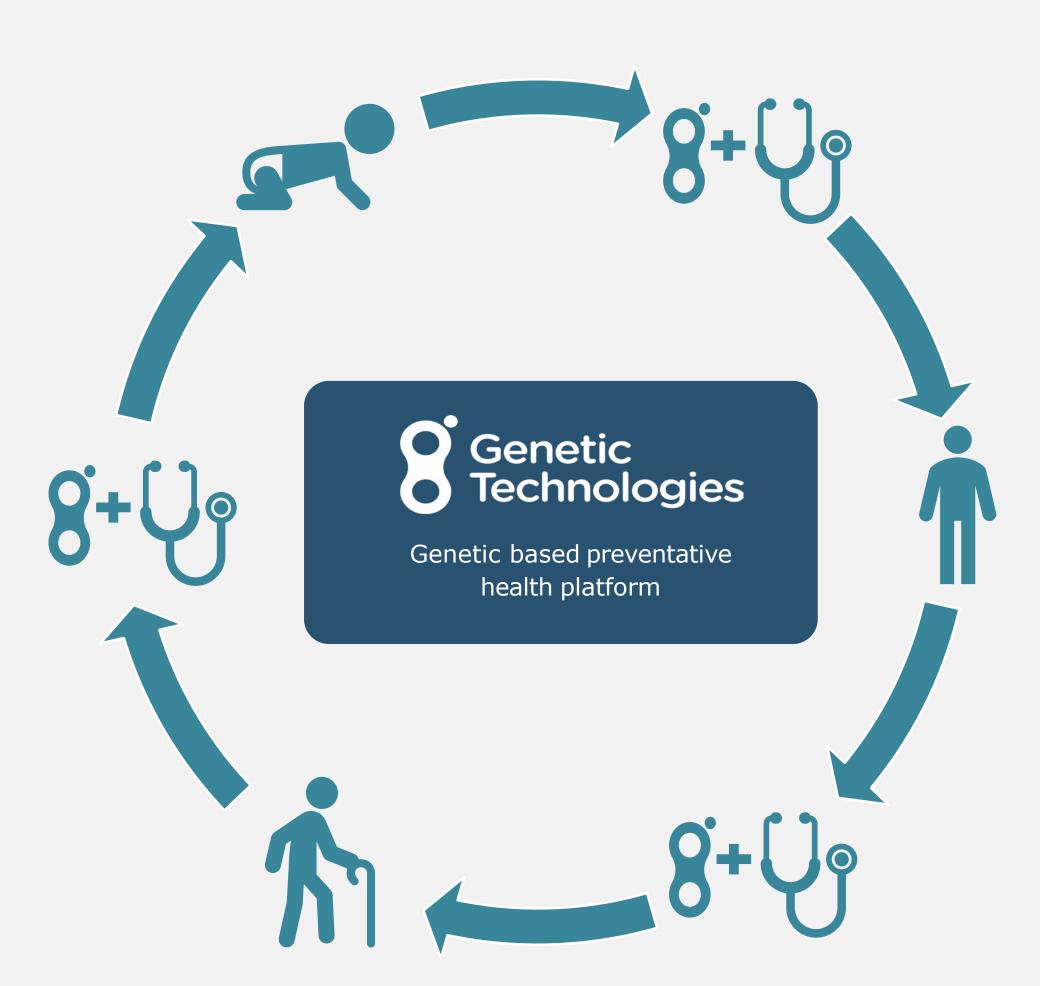
- Transitioned from one product two years ago to 10 products in development
  - Ability to accelerate the development of new products and tests
  - Expanding into reimbursable space

#### • Focused on:

- Establishing business leadership through peer reviewed publications, providing reimbursable products and leveraging key opinion leaders
- Providing individuals with management and lifestyle insights that can be implemented 15-20 years before onset of disease to extend quality of life through:
  - Products that are designed to improve medical and lifestyle outcomes mediated through environmental changes, supplements and medications where appropriate

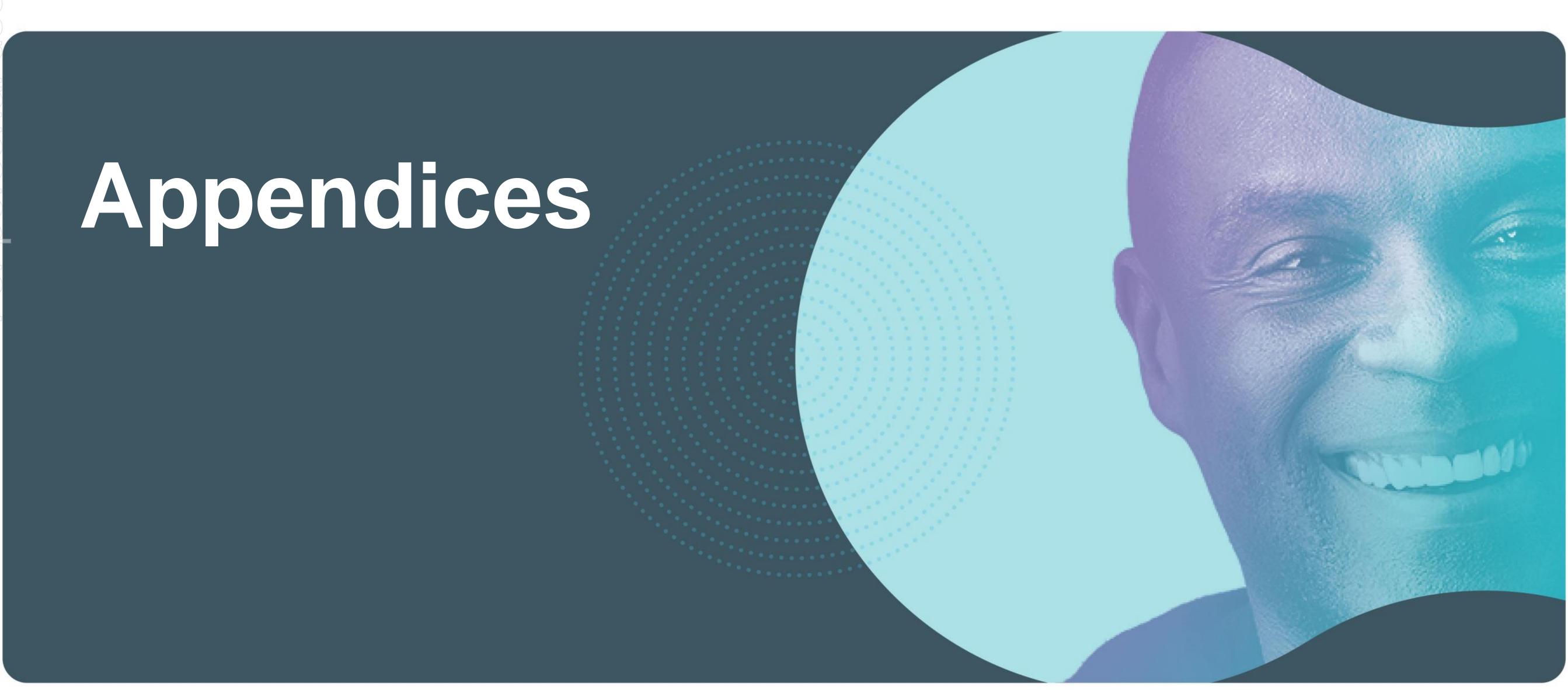
#### Controlled operational costs

- Only ~10% increase associated with expanded product base to date
- Continually evaluating further opportunities
  - Leveraging in market products to enhance product offering (ie. Taliaz)



# Thank You

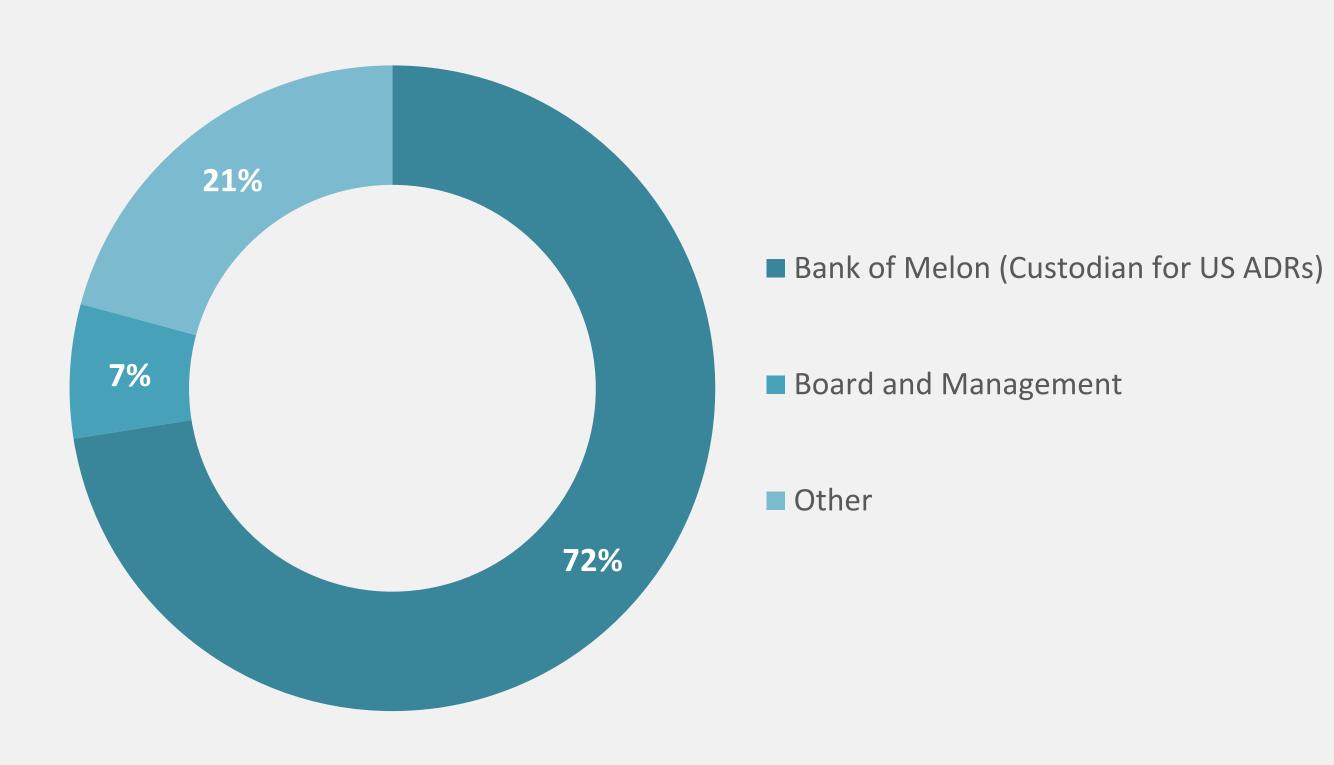




# **Corporate Overview**



Top 50 share registry breakdown



## **Dual Listed on the ASX and Nasdaq**

#### **Financial Information**

Share price (AUD) as at 5 January 2021	0.9c
ADR price (USD) as at 5 January 2021	\$4.02
Ord Share on Issue (M) <sup>1</sup>	8,261
ASX 52-week trading (low/high)	0.3/1.4c
Nasdaq 52-week trading (low/high)	\$1.41/10.30
Market Cap (A\$M)	74.35
Cash (30 September 2020)	\$18.1m
Debt (30 September 2020)	nil

<sup>1.</sup> American Depository Receipts (ADRs) are interchangeable via custodian Bank of Mellon with 70% of stock held in the USA

<sup>2.600</sup> shares on the ASX equate to 1 ADR (American Depository Receipts) in the USA which are interchangeable via custodian Bank of Mellon

# Our board





Dr. Jerzy "George" Muchnicki
MBBS
Executive Director & Chief Executive Officer (Interim)



Dr. Lindsay Wakefield

MBBS

Non – Executive Director



Mr. Peter Rubinstein

BSc, BEc, LLB

Chairman - Non – Executive Director



Mr Nick Burrows

B.Com, FAICD, FCA, FGIA, FTIA, F Fin

Non – Executive Director

# **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 (PRS) - A polygenic risk score tells you how a person's risk compares to others with a different genetic constitution. However, polygenic scores do not provide a baseline or timeframe for the progression of a disease. For example, consider two people with high polygenic risk scores for having coronary heart disease.

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.

**Genome Wide Association Studies (GWAS)** - an approach used in genetics research to associate specific genetic variations with particular diseases. The method involves scanning the genomes from many different people and looking for genetic markers that can be used to predict the presence of a disease. Once such genetic markers are identified, they can be used to understand how genes contribute to the disease and develop better prevention and treatment strategies.