



**NASDAQ: GENE**  
**Biotech Showcase**  
14 January 2020  
San Francisco

# Forward looking statements

This presentation may contain forward-looking statements within the meaning of Section 27A of the U.S. Securities Act of 1933 and Section 21E of the U.S. Securities Exchange Act of 1934 with respect to the financial condition, results and business achievements/performance of Genetic Technologies Limited and certain of the plans and objectives of its management. These statements are statements that are not historical facts.

Words such as “should”, “expects”, “anticipates”, “estimates”, “believes” or similar expressions, as they relate to Genetic Technologies Limited, are intended to identify forward-looking statements. By their nature, forward-looking statements involve risk and uncertainty because they reflect Genetic Technologies’ current expectations and assumptions as to future events and circumstances that may not prove accurate. There is no guarantee that the expected events, trends or results will actually occur. Any changes in such assumptions or expectations could cause actual results to differ materially from current expectations.

# Who we are

## Genetic Technologies is a leader in genomics

- Over a decade of R&D surrounding the development of polygenic risk scores
- Developing risk prediction platforms for major oncological, metabolic and degenerative diseases
- Strong scientific leadership under Dr Richard Allman – a pioneer in the development of polygenic risk scores
- In collaboration with some the world's most prestigious universities and medical institutes
- Delivering better outcomes at a lower cost to the patient and the medical system
- Supported by a deep, robust IP portfolio
- **In 2020 will offer the most comprehensive suite of polygenic risk assessment tests on the market**

Dual listed on the ASX (GTG) and Nasdaq (GENE)



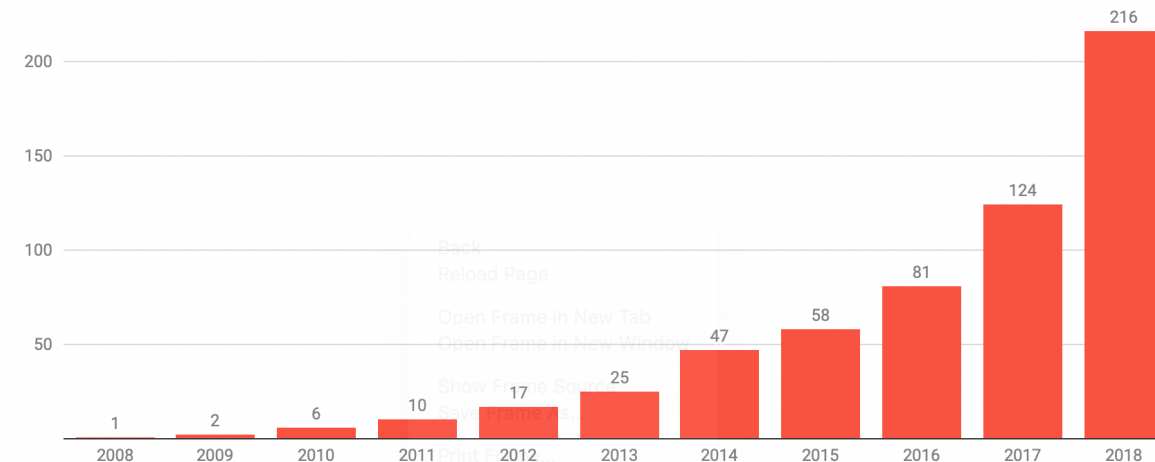
# The human genome

In 2003, humanity completed perhaps its most ambitious voyage of exploration when scientists mapped the human genome – the three-billion-plus pairs of DNA that make us human.

Advances in genomic epidemiology and sequencing technology will influence the way physicians practice medicine in the 21st century with polygenic predictors used to identify individuals at risk for common chronic conditions.

## Risk prediction research

A growing number of reports try to predict common disease risk from DNA\*



\*Number of papers mentioning "polygenic risk score" in title or abstract.

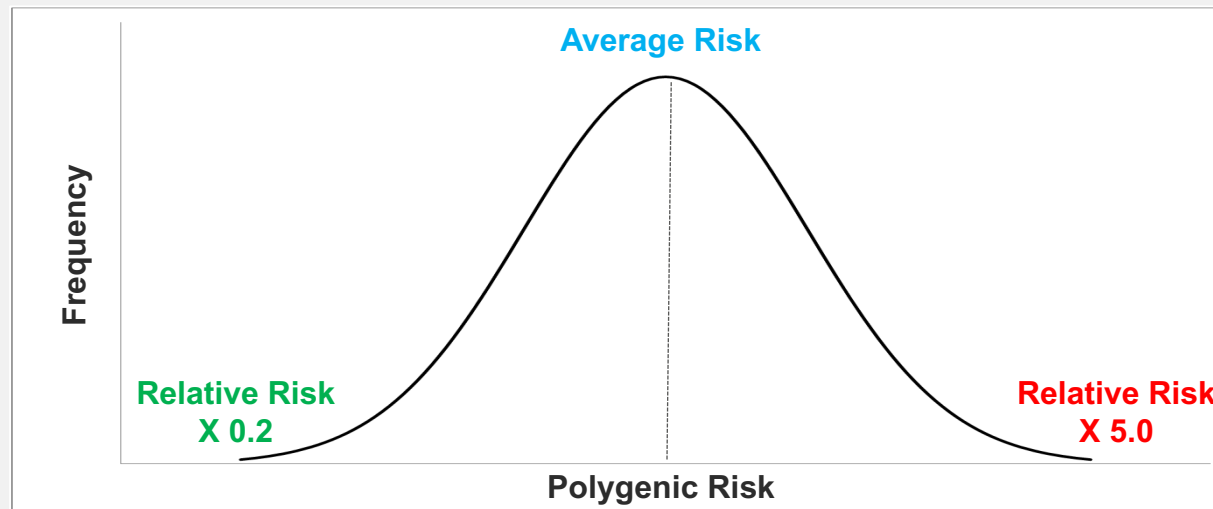
Chart: MIT Technology Review • Source: Credit: PubMed, National Center for Biotechnology Information • [Get the data](#) • Created with [Datawrapper](#)



# Polygenic Risk Score

## What is it?

- Most common complex diseases are a result of not one or a few genes, but many acting in concert
- Polygenic Risk Score is a DNA based risk assessment (screening) tool that weighs a person's odds of developing common complex diseases by inspecting DNA information spread across the genome
- Genomic and non-genomic factors are considered including lifestyle and family history
- Validated risk stratification method (GWAS)
- Identifies high-risk individuals for earlier and more frequent screening



# Polygenic Risk Score

**How do Polygenic Risk Scores differ from genetic testing (e.g. BRCA in breast cancer)?**

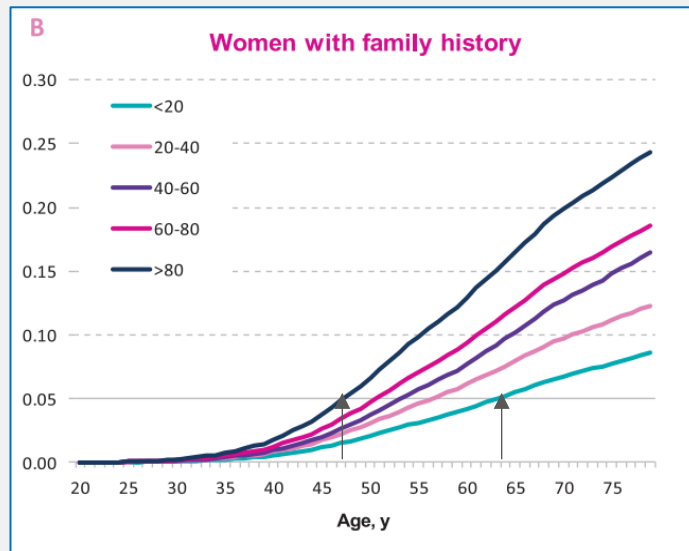
- Genetic testing only captures hereditary forms of disease (e.g. inherited cancer risk)
- Polygenic Risk Scores capture sporadic (non-inherited) disease, the most common form of all diseases
- It allows for more personalized, precision medicine

**Polygenic Risk Scores, validated by GWAS (millions of data points), represent the evolution of disease screening and ultimately prevention.**



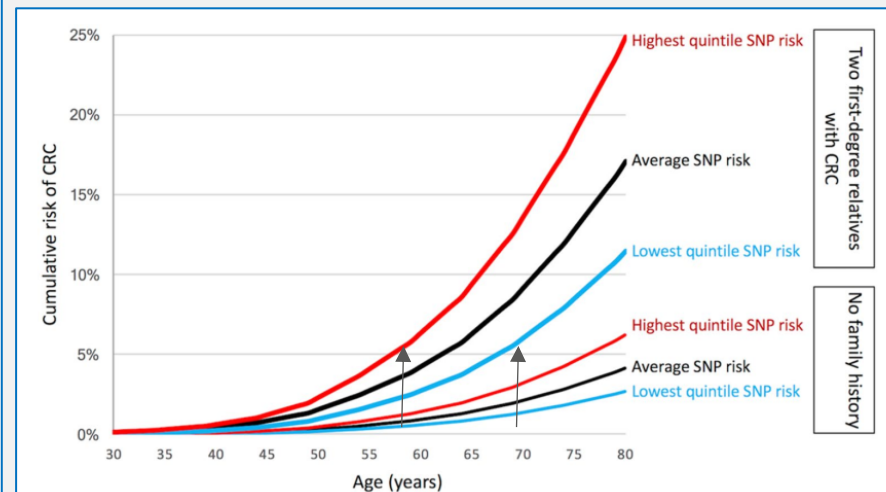
# The justification of using Polygenic Risk Score to inform earlier screening is similar across disease types

## Breast cancer



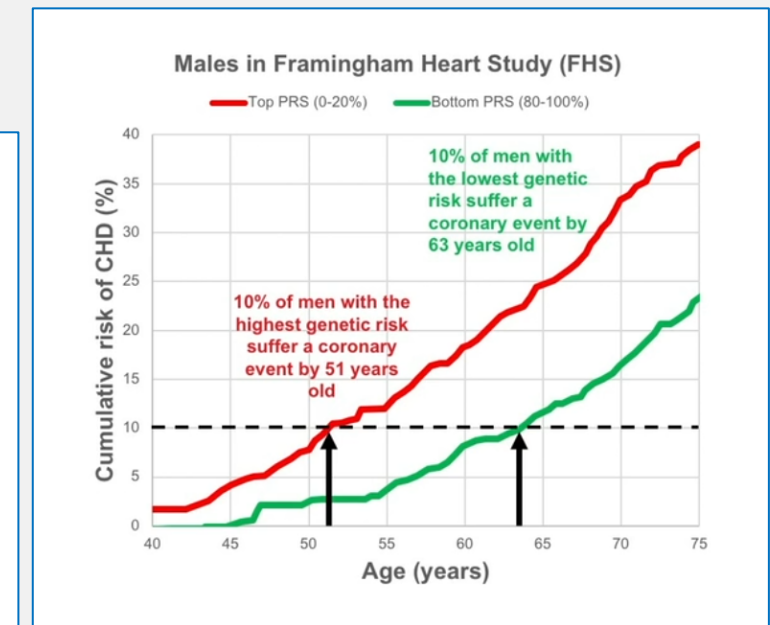
Mavaddat et al. (2015) JNCI

## Colorectal cancer



Jenkins et al. (2019) Familial Cancer

## Coronary heart disease



Abraham et al. (2016) Eur Heart J.

# The unmet need

- Current genetic testing only captures hereditary forms of disease
- Current system is binary - everyone is tested regardless of personal risk status
- Currently system is inefficient with a one-size-fits-all policy based on averages
- Unable to clearly identify high risk groups
- Most testing commences at 50 however approximately 20% of diseases occur before 50
- Doesn't pick up interval cancers - 45% of new cancers which occur between screenings

**Until today we haven't had a product that predicts risk and detects disease in early stage. Now that we have it, it needs to be integrated into the current health management system.**



# Intellectual property is a core advantage

## GTG has a strong patent portfolio covering the breast cancer risk assessment test

### 5 Patents granted in the US

- 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

### 7 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

# Operational overview

## Genetic Technologies Limited

Melbourne, Australia

- Technical and corporate support
- CLIA approved laboratory

## Phenogen Sciences Inc.

Charlotte, North Carolina, USA

- Clinical and customer support
  - Sales and marketing
- Liaison for US collaboration

# 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

Non – Executive Director



**Mr Nick Burrows**

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

Non – Executive Director

# Our vision

- Identify and manage patients who are at high risk of developing major life threatening diseases
- Implement the current protective medical strategies in the best way possible for identified high risk groups via:
  - targeted screening
  - lifestyle changes
  - chemoprophylaxis and/or surgical intervention as determined by clinicians
- Utilise our powerful predictive/indicative technology as the cornerstone of a preventative medical system where early detection leads to cost effective and life saving outcomes





# Product overview



# Product range and status

- Our breast and colorectal cancer products are market ready
- T2D and CV tests are in final stages of development

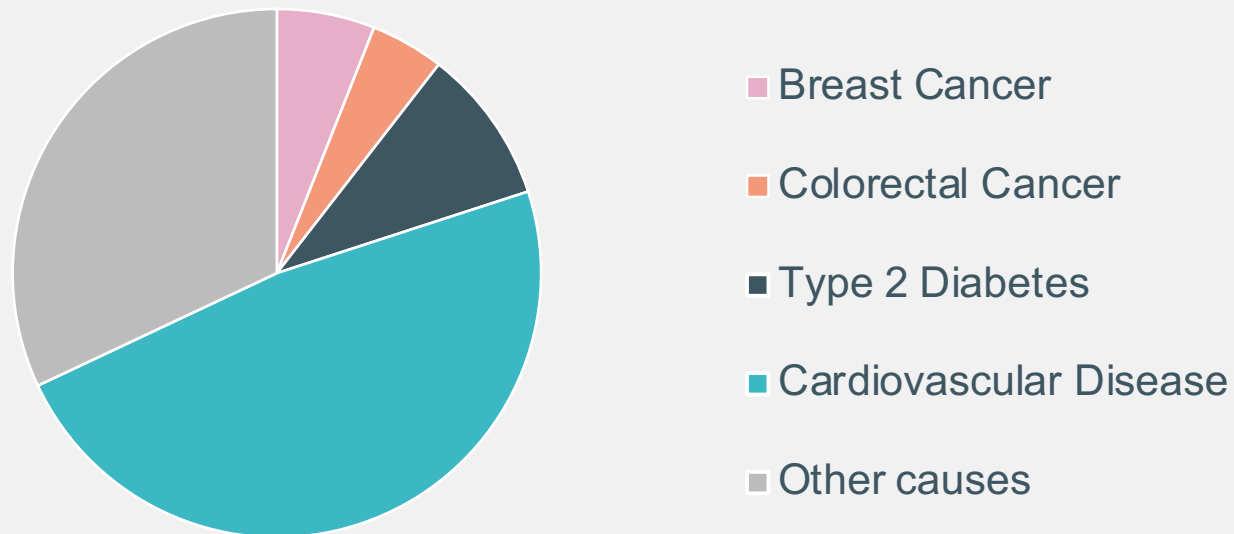


\* Tests are developed and market launch is scheduled.

# Disease coverage

- Our product development strategy aims to provide coverage of the most significant causes of morbidity and mortality in the US
- It covers up to 70% of causes of mortality

## Incidence of underlying causes of mortality in the US



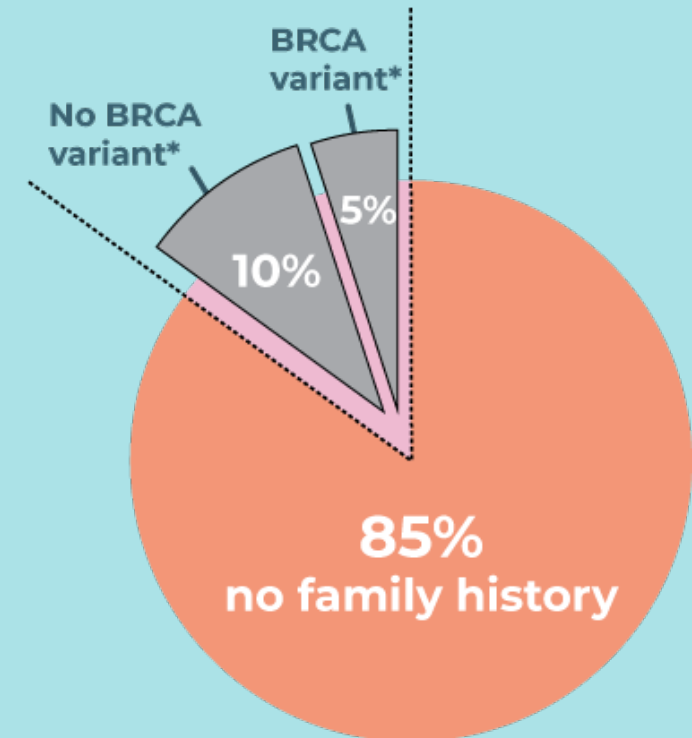


# GeneType for Breast Cancer



# Breast cancer at a glance

- **1 in 8** women will get breast cancer in their lifetime
- Every year approximately **270,000** women will be diagnosed with breast cancer
- **25%** of breast cancers develop **before the age of 50** (average age 62)
- **85%** of women have no family history of breast cancer
- **10% have a family history but no pathogenic variants**, such as BRCA
- Only **5% of women with breast cancer have a pathogenic variant**, such as BRCA



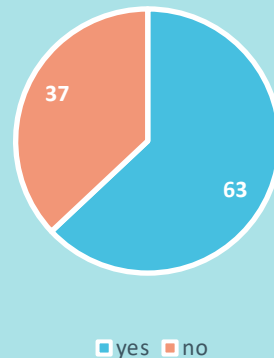
\* Pathogenic variants include those in moderate and high penetration, including but not limited to ATM, BRCA1/2, BRIP1, CDH1, CHEK2, PALB2, PTEN, TP53.

# Average (asymptomatic) woman at a glance

- **Majority of women** do **NOT** have family history of breast cancer
- Misconception that lack of FH means lower risk of breast cancer thus they tend be less screen-compliant

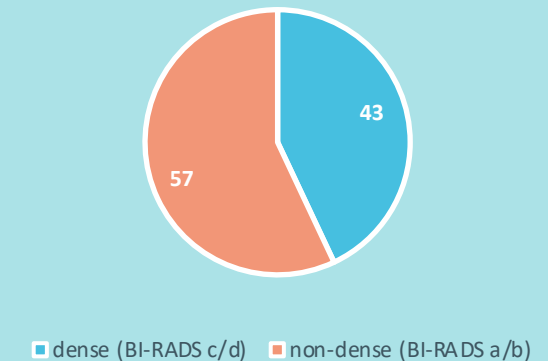
**Over 1/3 of women  
are not screen-  
compliant**

Up-to-date mammogram



**Nearly half of all  
women have a  
significant risk factor:  
dense breast tissue**

Percentage of women (40+)  
with dense breast tissue



# GeneType for Breast Cancer

- **GeneType for Breast Cancer (GeneTypeBC)** is a first-to-market, clinically validated genetic risk assessment for non-hereditary (sporadic) breast cancer which represents up to 90% of all breast cancers
- It is the world's first validated genomic test to accurately predict risk of disease by combining the information contained in DNA with family history and mammography data to create a powerful new tool in the battle with breast cancer



• **Simple cheek swab** that helps determine a woman's risk of developing breast cancer

• **First test of its kind to be clinically validated** to evaluate risk for sporadic breast cancer

• Validated for use in Caucasian, African American and Hispanic women **over age 35**

**GeneType's technology covers 95% of women**

# Targeted screening and prevention

**GeneType for Breast Cancer enables the targeting of limited resources to women who are most likely to develop breast cancer**



## Screening

More frequent mammograms or MRIs



## Medication

Selective estrogen receptor modulators (SERMs) or aromatase inhibitors (AIs)



## Lifestyle

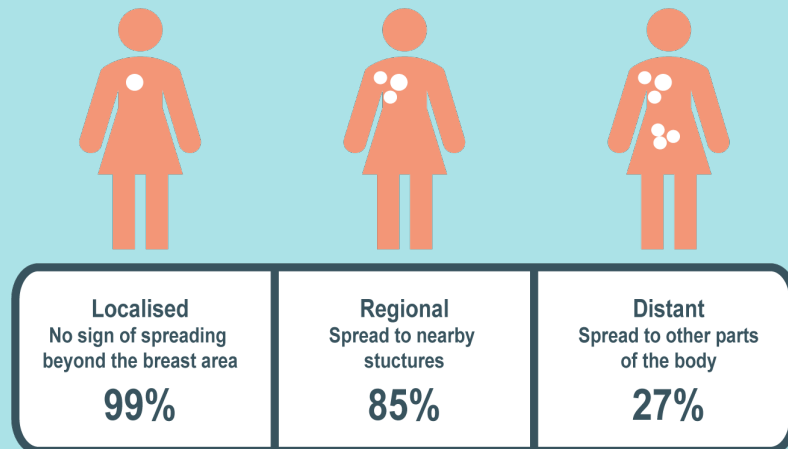
Weight loss, alcohol consumption, physical activity



# Identify at-risk women = Better outcomes

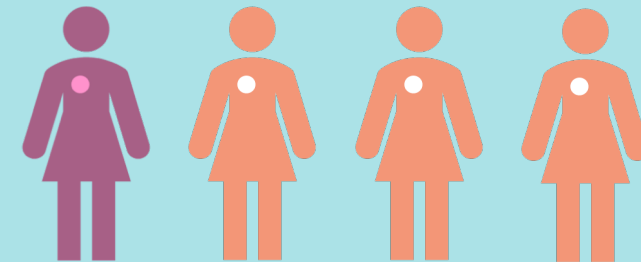
## Screening

- By implementing enhanced surveillance of high-risk individuals, you enable clinicians to improve breast cancer detection
- 5-year survival rates dramatically improve when breast cancer is diagnosed before spreading to other parts of the body



## Risk reduction

- By qualifying high-risk women for risk reducing medications, you enable clinicians to reduce breast cancer incidence by upwards of 50%
- Nearly 1 in 4 woman over 40 are at increased risk of breast cancer based on her 5-year risk score (>1.66%)



# Early diagnosis = Less expensive treatment

**First year  
treatment costs  
for breast cancer**

**Stage I.....\$ 55,000**

**Stage II.....\$103,000**

**Stage III and IV.....\$150,000+**

USD, study based on US patients, 2003-2010  
<https://journals.plos.org/plosone/article/figure?id=10.1371/journal.pone.0207993.t001>

# Wider age and population coverage

- GeneType for Breast Cancer tests individuals before age of 35 and covers the African American and Hispanic population

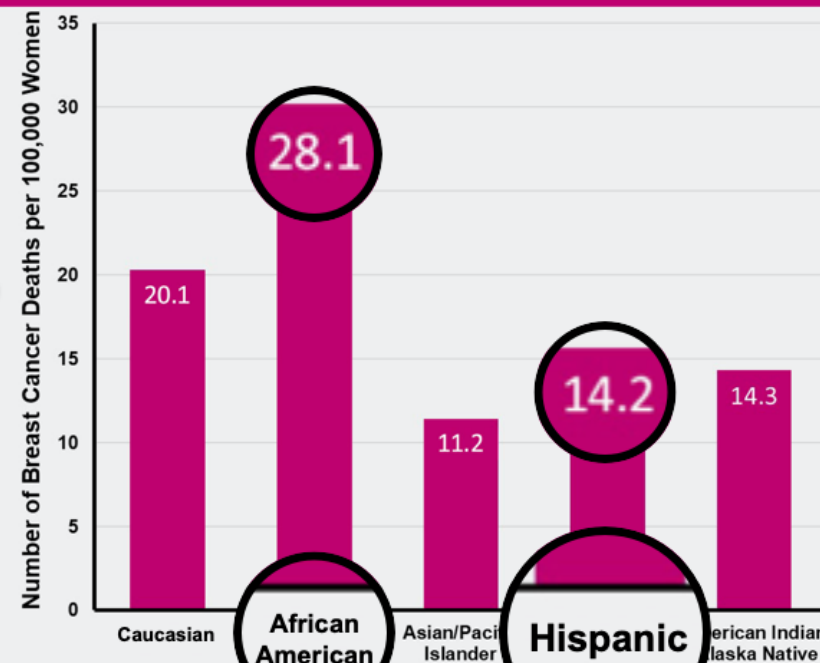
**Table 1. Estimated New Female Breast Cancer Cases and Deaths by Age, US, 2017**

Age	In Situ Cases		Invasive Cases		Deaths	
	Number	%	Number	%	Number	%
<40	1,610	3%	11,160	4%	990	2%
40-59	12,440	20%	36,920	15%	3,480	9%
60-69	17,680	28%	58,620	23%	7,590	19%
70-79	17,550	28%	68,070	27%	9,420	23%
80+	10,370	16%	47,860	19%	8,220	20%
80+	3,760	6%	30,080	12%	10,910	27%
<b>All ages</b>	<b>63,410</b>		<b>252,710</b>		<b>40,610</b>	

Estimates are rounded to the nearest 10. Percentages may not sum to 100 due to rounding.

©2017, American Cancer Society, Inc., Surveillance Research

**Breast Cancer Mortality in U.S. Women by Race and Ethnicity, 2012-2016**



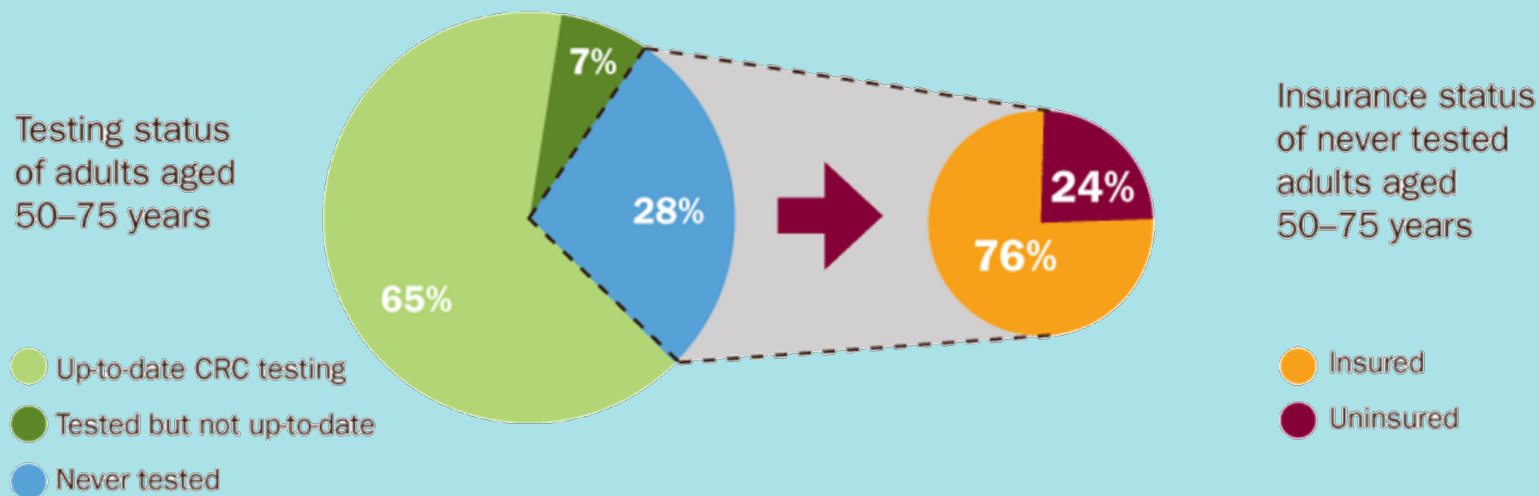


# GeneType for Colorectal Cancer



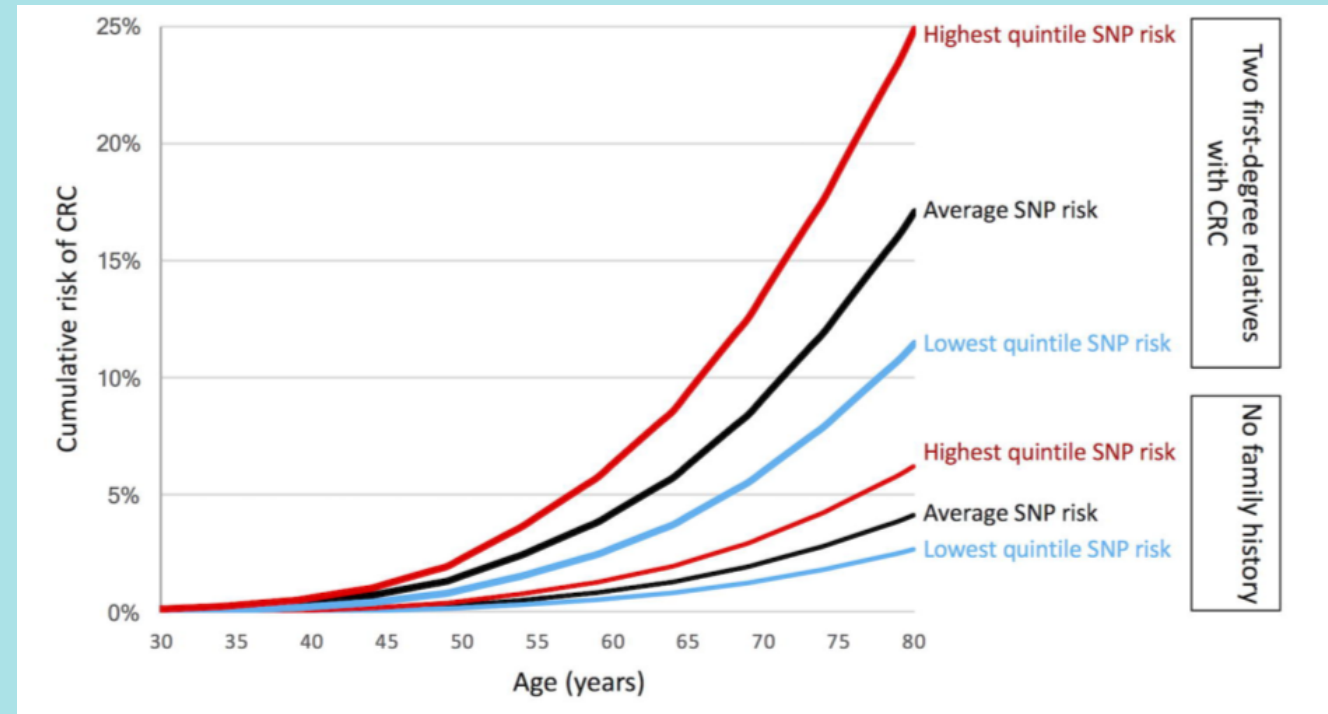
# Colorectal cancer at a glance

- **150,000** people are diagnosed with colorectal cancer every year in US
- **1 in 20 will get colorectal cancer** in their lifetime
- Screening begins at **45**
- Approximately **10%** of colorectal cancer develop **before the age of 50**
- More than **50%** of colorectal cancer are first identified in late stage
- **69% 5-year survival rate**
- Late stage survival
- **Over 1/3 of population is not tested**



# Distribution of lifetime colorectal cancer risk stratified by polygenic risk and family history

- Risk of acquiring the disease as a high-risk individual is earlier
- Family history is potent in identifying risk
- Can't look at genomics alone



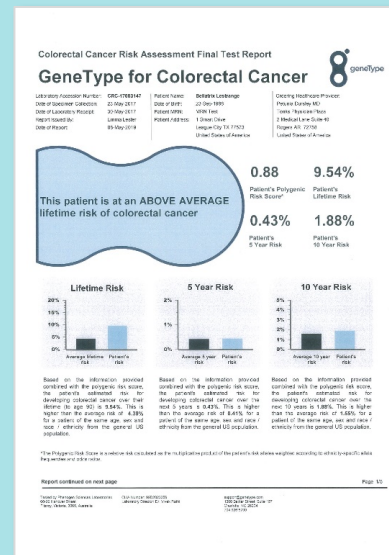
# GTG has developed a world-first polygenic risk test for colorectal cancer

Easy-to-use test solves the compliance problem



Simple cheek swab test

Risk stratification enables precision screening and personalised prevention



Report sent to your doctor

Clinically actionable results

5-year, 10-year and lifetime risk

Informs screening and health monitoring for those most at risk

**GeneType's technology covers 95% of colorectal cancer**



# Commercialization Strategy



# We aim to touch as many lives as possible through partnerships (network)

## Partnership

Partner with genomics market leaders to integrate Genetic Technologies' tests into their testing platforms:

- White label/OEM arrangements
- Royalty based
- Shared expense in prosecution of infringement of Genetic Technologies' IP

## Clinics/CIT

Q1 2020 Launch GeneType product line:

- Consumer initiated
- \$249 price point
- Leverage existing clinician networks / pathology groups
- Further validation with Tgen:
  - Utility
  - Reimbursement

# Partnering as an OEM/white label test

**Genetic Technologies is seeking to market its polygenic risk score tests as part of a wider offering by established genomic testing market leaders**

## **Our partner should :**

- Be a market leader in CIT or DTC genomics space
- Have a large pool of genomes available for testing using Genetic Technologies' tests both for R&D and commercial purposes
- Have a demonstrated interest in expanding their offering from hereditary genomics to Polygenic Risk Scores
- Have a capability to work with Genetic Technologies to prosecute its IP position

## **We seek to:**

- Grant an OEM license to our tests on a royalty/ profit share basis
- Develop new PRS based tests using partners' genomics databases
- Exclusively represent our partner in our native market of Australia

# Consumer Initiated Testing


## More people are taking control of their health

### **CIT Will allow Genetic Technologies to offer Polygenic Risk Score tests directly to consumers**

- Genetic Technologies is in discussions with a leading provider of CIT services that will Provide outsourced clinical and logistical backbone to our diagnostics operations
- Anticipate a \$249 price point
- Will allow Genetic Technologies to access major markets without a need for a large and expensive sales force
- We are currently negotiations with US high visibility brand ambassadors to complement this strategy



## Existing network of clinics

- Genetic Technologies plans to leverage existing relationships with its network of clinics
  - Strong demand from clinicians familiar with the products and the value proposition of Polygenic Risk Testing
  - Clinics used to offer Genetic Technologies' previous product, BrevaGen
  - 20+ clinics in 12 states
  - Clinics span wide breadth of specialties including:
    - Primary women's healthcare
    - OB/GYN
    - Breast surgical oncology
    - High-risk cancer clinics
- 
- A map of the United States with red pushpins indicating clinic locations. The pushpins are located in Washington, Oregon, California, Nevada, Arizona, Idaho, Montana, Wyoming, North Dakota, South Dakota, Nebraska, Kansas, Oklahoma, Texas, Louisiana, Mississippi, Alabama, Georgia, Florida, and New York.



# Validation, Collaboration and Academic Partnerships

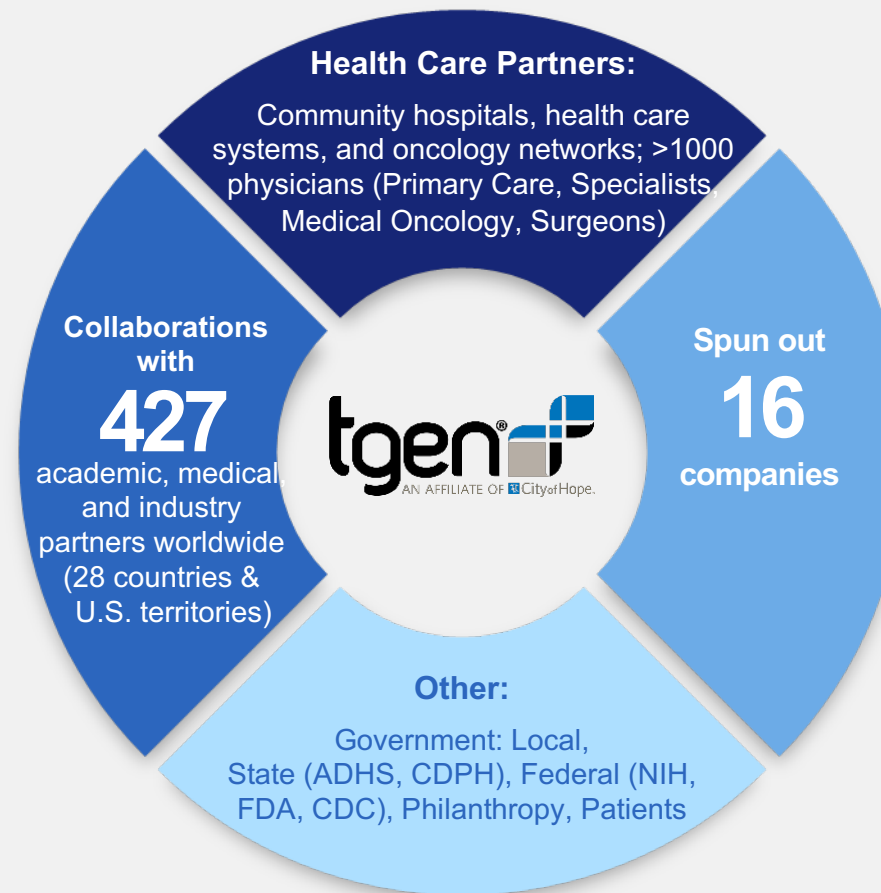
# Translational Genomics Research Institute (TGen): Collaborative Network

## Background

- Est. 2002
- Non-profit (501c3)
- Patient-focused clinical & basic research
- Pioneers in precision genomic medicine
- Expertise includes: Clinicians, laboratory and computer scientists, data analysts, and business development
- Joined City of Hope in Nov. 2016

## Highlights

- Performing personalized cancer treatment since circa 2008
- 1<sup>st</sup> polygenic risk score paper published in 2008 (NEJM)
- Performing whole genome sequencing to inform cancer therapy since circa 2010
- 1<sup>st</sup> precision medicine trial for children's cancer published in 2014
- Regularly conduct 1<sup>st</sup> in human clinical trials
- Supercomputer built specifically for genomic applications
- Developer and early adopter of paradigm shifting technologies



## Areas of Disease Focus

- Oncology
- Neurology
- Rare Childhood Disorders
- Diabetes
- Infectious Disease

## Research Specialties

- Population Genetics
- Cancer Prevention and Early Detection
- Rare (Childhood) Disease
- Circulating Biomarkers
- Quantitative Medicine
- Infectious Disease
- Tumor Profiling/Drug Selection
- Clinical Trials

## Basic Computing to High Performance Computing

## Basic Data Analysis to Quantitative Medicine

# Collaboration is a key market advantage

## The University of Melbourne

- Australia's peak research-intensive institution, ranked 32<sup>nd</sup> globally

## Our collaboration with The University of Melbourne was awarded an NHMRC grant

- Research investigation to assess the improvement in breast cancer risk prediction using polygenic risk
- Led by Professor John Hopper
- National Health and Medical Research Council is Australia's peak funding body for cutting-edge research

### Professor John Hopper

- PhD in Mathematical Statistics
- NHMRC Senior Principal Research Fellow
- Director (Research) of the Centre for Epidemiology and Biostatistics in the School of Population Global Health at The University of Melbourne
- Published more than 700 papers



**This work has established GTG as a global leader in polygenic risk research and development**

# Research into clinical applications

GTG has an agreement in place with **Memorial Sloan Kettering (MSK)** and **University of Cambridge**

- The research is led by Mark E. Robson, MD, Chief of Breast Medicine Service, Memorial Sloan Kettering
- MSK is the world's oldest and largest cancer treatment and research institution
- Memorial Sloan Kettering was ranked second among hospitals specializing in cancer treatment in the US
- The University of Cambridge's UK Institute is a world leading cancer biotech center



**Genetic Technologies partners with world-leading research hospitals to develop the clinical use of polygenic risk scores in treatment decisions**



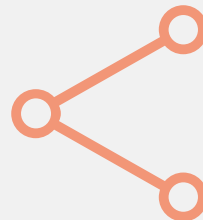
# Other key partnerships

## Ohio State University (Columbus, Ohio)

- Research collaboration exploring polygenic risk as a means to more informed decision-making for women with BRCA mutations
- Led by Amanda Toland, Director of Clinical Genetics and a leader in the field of breast cancer risk assessment

## Nurses' Health Study

- Harvard University prospective study of the risk factors for major chronic diseases in women
- Collaborating with principle investigators to validate new risk models for breast cancer



# Genetic Technologies' snapshot



- Current market cap as of 9/01/2020: \$27.9M
- Dual listed ASX/NASDAQ
- App. No. Shares on issue: 4,000,000,000 (ADR @ 600:1)
- \$US 3M cash as of 31 December 2019
- Company funded out to Q1 2021 based on current business plan



# An exciting year ahead for Genetic Technologies



Upcoming catalysts aim to increase revenues and generate shareholder value

Q1 2020

- GeneType for Breast Cancer and GeneType for Colorectal cancer market ready
- Start US Sales and marketing through existing clinician network
- Start of clinical utility study in conjunction with Tgen

Q2 2020

- Launching CIT operations
- Complete work on type-2 diabetes risk test

H2 2020

- Complete work cardiovascular risk test
- Closing of OEM agreement in the US
- Introduce 2 additional tests for a total of 4 tests
- Expansion of Tgen collaboration based on clinical utility results

# Thank you



**Dr George Muchnicki**  
**Executive Director and Interim CEO**

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