Genetic Technologies

# Genetic Technologies

## Company Profile

01 May 2019

# 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

## Research and Development leader in the genomics sector

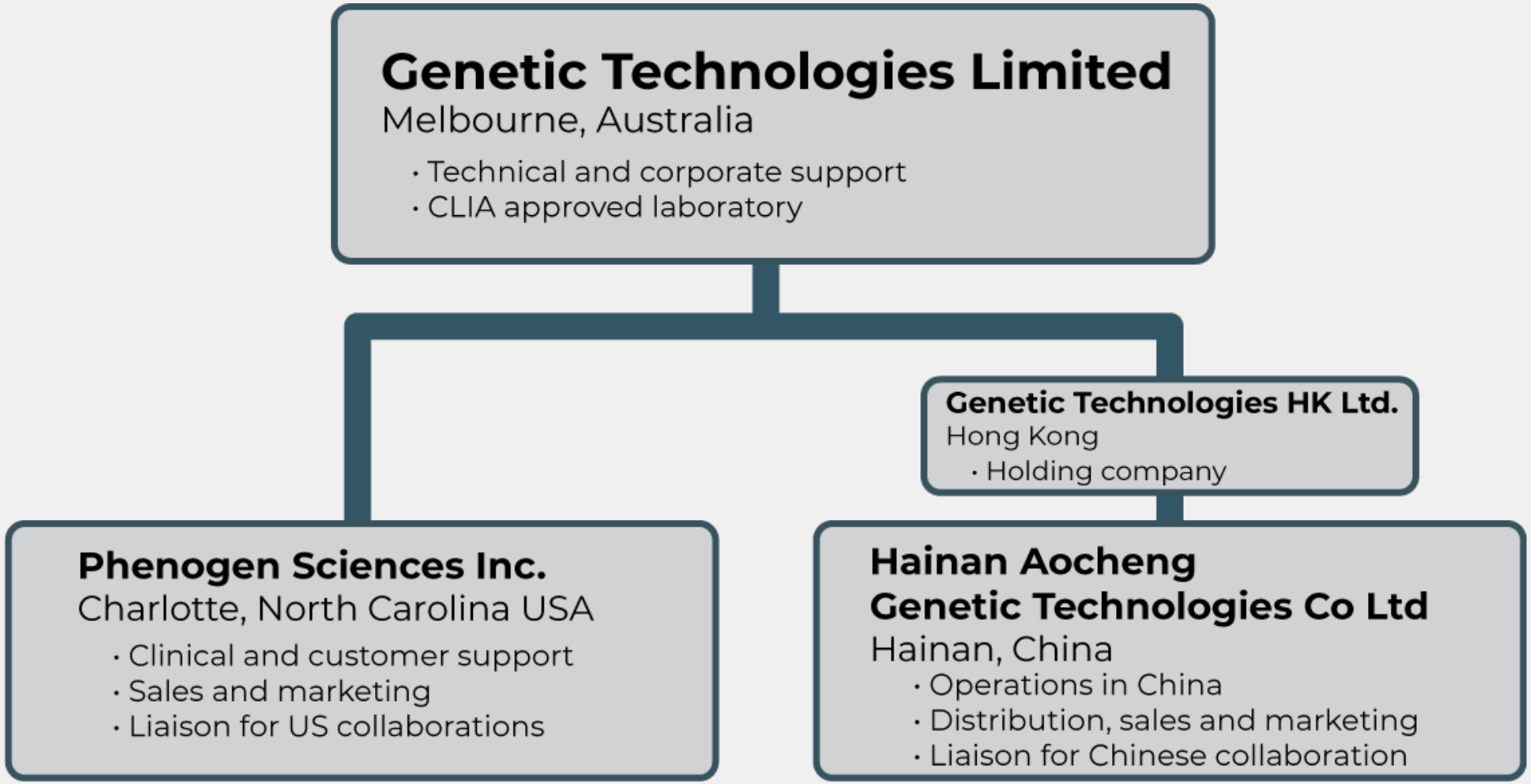
- Developing and commercialising a suite of genetic risk assessment products to prevent morbidity and mortality across a range of diseases
- 20 years experience bringing genomics products to market
- Progressive R&D and commercialisation partner to
  - Universities
  - Research organisations
  - Companies exploring new delivery technologies for genomic solutions

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

# Our vision

- To improve health outcomes for people around the world by providing individuals and their physicians with the risk assessment tools to develop personalised health management plans for early detection and treatment of chronic disease
- To continually strive to maintain our standing as a global leader in genomics by investing in our own research capabilities and by forming partnerships with experts from world class organisations

# GTG corporate overview



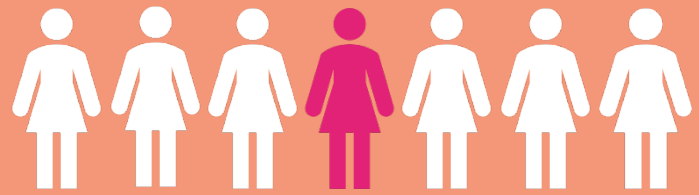
# Our genetic test predicts a woman's risk of developing breast cancer

## BREVAGen*plus*® is a first-to-market, clinically validated genetic risk assessment for non-hereditary (sporadic) 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

# Precision medicine

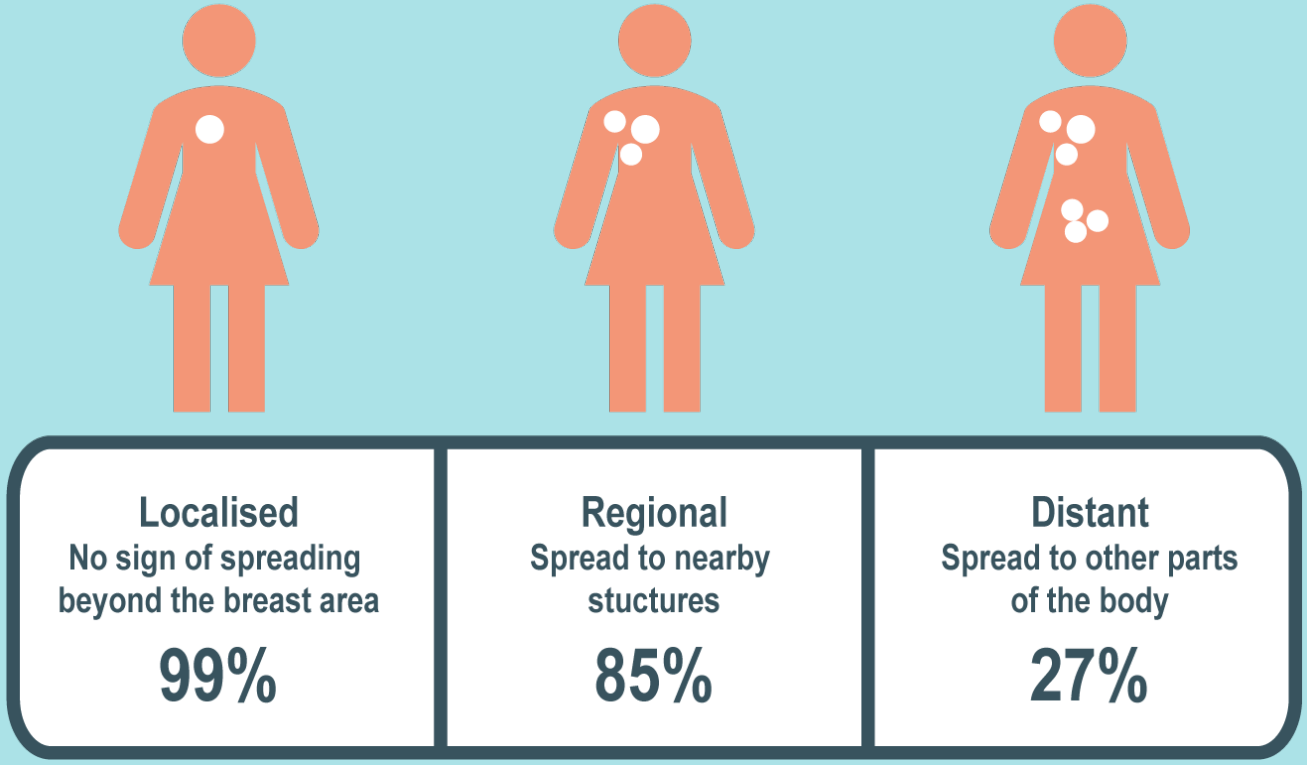
- 1 in eight women will get breast cancer in their lifetime
- Screening programs that test all women at the same intervals will be overscreening 7 women and underscreening 1 woman



- Our risk assessment test offers health policy regulators and clinicians the potential for more efficient use of screening resources

# Early detection = better outcomes

## 5 year survival rates dramatically improve when breast cancer is diagnosed before spreading to other parts of the body




https://www.cancer.org/cancer/breast-cancer/understanding-a-breast-cancer-diagnosis/breast-cancer-survival-rates.html

# Early diagnosis = less expensive treatment



**First year treatment costs for breast cancer**

| | |
|---|---|
| Stage I | $ 55,000 |
| Stage II | $103,000 |
| Stage III and IV | $127,000 |

USD, study based on US patients, 2003-2010

https://journals.plos.org/plosone/article/figure?id=10.1371/journal.pone.0207993.t001

# Targeted screening and prevention

**BREVAGen*plus*® enables the targeting of limited resources to women who are most likely to develop breast cancer.**

## Screening

More frequent mammograms or MRIs

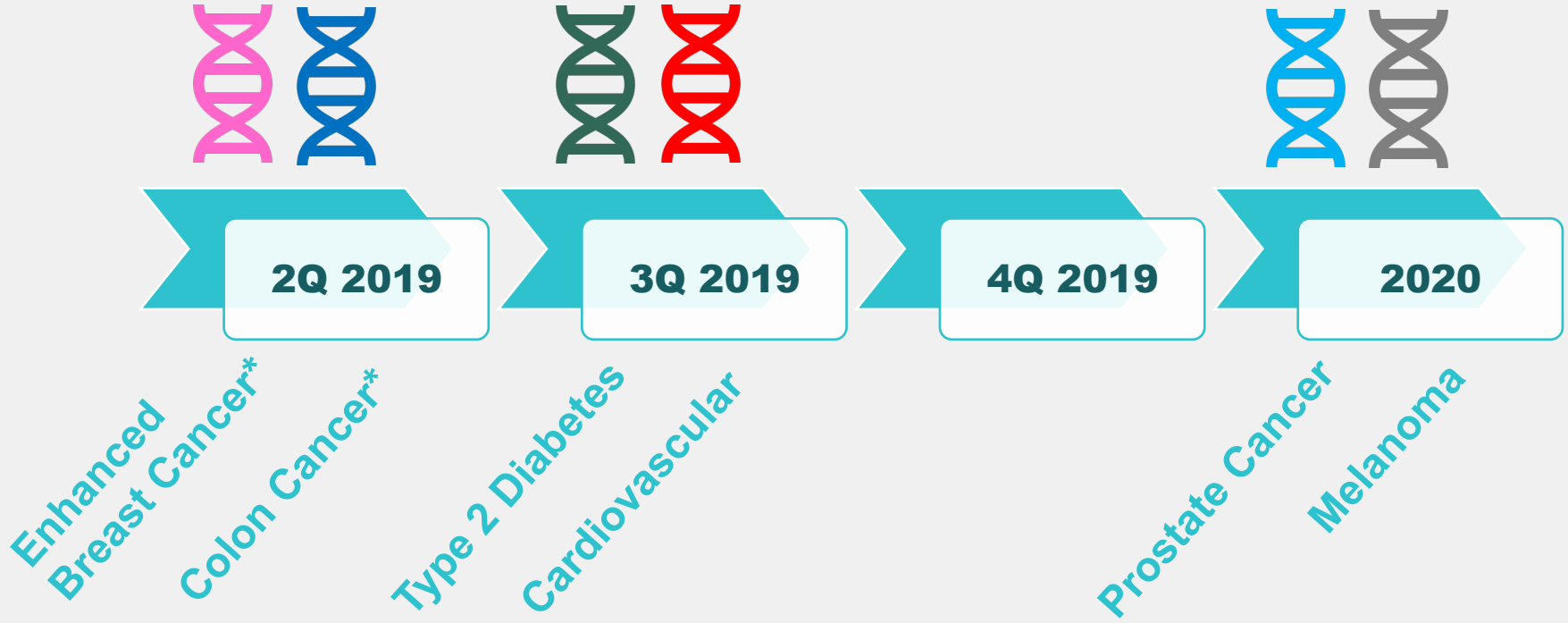
## Medication

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

## Lifestyle

Weight loss, alcohol consumption, physical activity

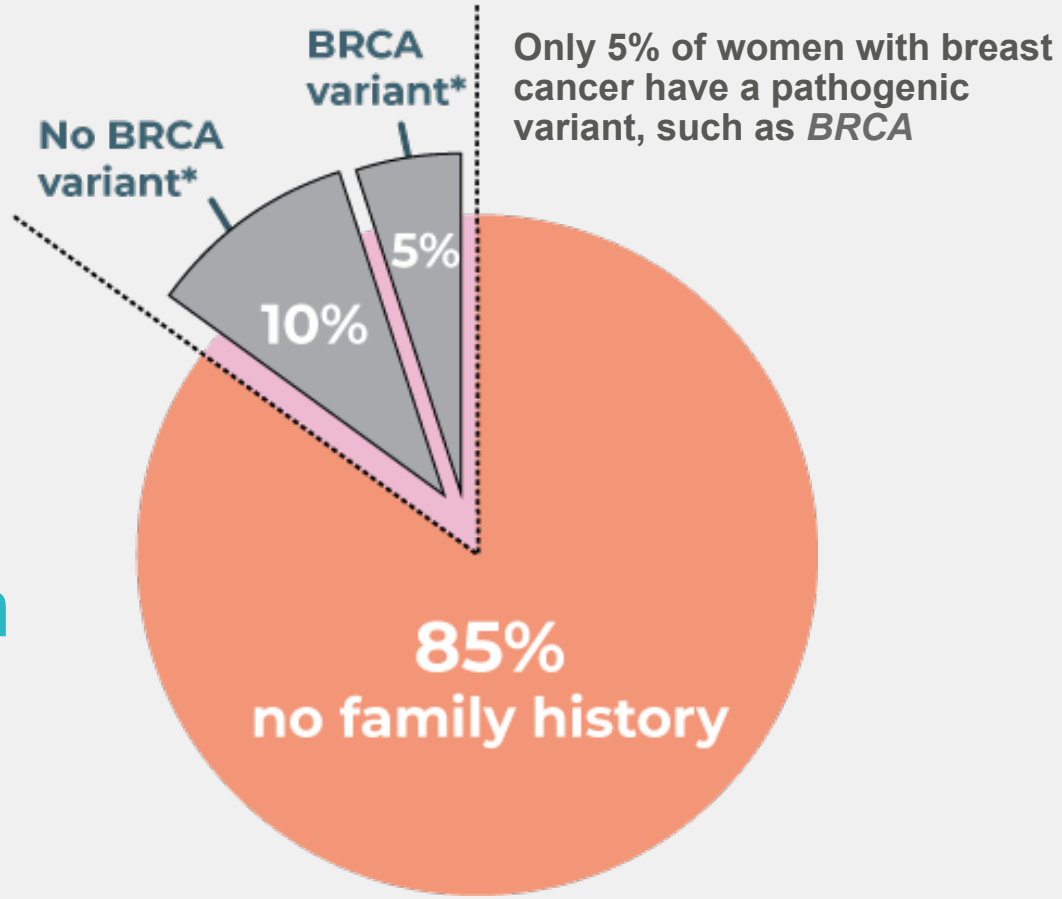
# We are developing new genetic screening tests




* Tests are developed and market launch is scheduled.

# GTG's enhanced breast cancer test covers 95% of women

- **85% of women have no family history of breast cancer**
- **10% have a family history but no pathogenic variants, such as *BRCA***



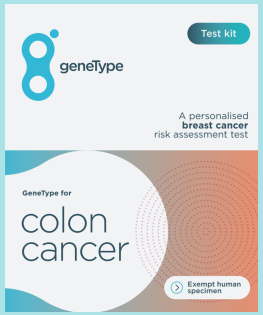

## Our test covers 95% of women

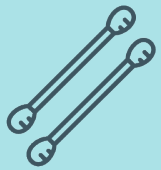


* Pathogenic variants include those in moderate and high penetration, including but not limited to ATM, BRCA1/2, BRIP1, CDH1, CHEK2, PALB2, PTEN, TP53.

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

## Easy-to-use test solves the compliance problem



Simple cheek swab test

Report sent to your doctor

## Risk stratification enables precision screening and personalised prevention


Colon Cancer Risk Assessment

Final Test Report

This patient is at ABOVE AVERAGE RISK of colorectal cancer.

Polygenic Risk Score* = xx

Patient's Lifetime Risk = xx%

5 Year Risk = xx%

10 Year Risk = xx%

Lifetime Risk

Based on the information provided combined with the polygenic risk score, the patient's estimated risk for developing colorectal cancer over their lifetime (to age 90) is XX%. This is higher than the average risk of XX% for a patient of the same age, gender, and race/ethnicity from the general US population.

5 Year Risk

Based on the information provided combined with the polygenic risk score, the patient's estimated risk for developing colorectal cancer over the next 5 years is XX%. This is higher than the average risk of XX% for a patient of the same age, gender, and race/ethnicity from the general US population.

10 Year Risk

Based on the information provided combined with the polygenic risk score, the patient's estimated risk for developing colorectal cancer over the next 10 years is XX%. This is higher than the average risk of XX% for a patient of the same age, gender, and race/ethnicity from the general US population.

* The Polygenic Risk Score is a relative risk calculated as the multiplicative product of the patient's risk alleles weighted according to ethnicity-specific allele frequencies and odds ratios.

- **Clinically actionable results**
- **5-year, 10-year and lifetime risk**
- **Informs screening and health monitoring for those most at risk**

# Collaboration with world-leading partners

# Development of Commercialization Strategy with TGen

## MOU Signed

GTG and TGen will cooperate in the development of a commercialisation strategy and infrastructure development for a suite of polygenic risk tests to be made available in the US market.

The collaboration will be wide in scope covering:

- Distribution Channel
- Reimbursement Strategy
- Further Research

# 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
- 1st polygenic risk score paper published in 2008 (NEJM)
- Performing whole genome sequencing to inform cancer therapy since circa 2010
- 1st precision medicine trial for children's cancer published in 2014
- Regularly conduct 1st 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

www.tgen.org

# The Distribution Channel



## The TGen collaboration opens up a number of potential distribution channels:

**I. Major US Healthcare Systems**

Distribution opportunity: Health care system test availability

**II. National Cancer Centers**

Distribution opportunity: Testing of cancer patients an family members

**III. Physician networks**

Distribution opportunity: Physician test ordering

**IV. Large employers/Self-insured**

Distribution opportunity: Employee health and wellness programs

# The Distribution Channel



**V. Disease consortiums**

Distribution opportunity: Clinical validity and clinical utility studies

**VI. State Government**

Distribution opportunity: Public health department "endorsement;" Public policy; Clinical utility studies

**VII. Federal Government**

Distribution opportunity: Regulatory and or policy filings, requirements, or changes

# The Tgen Clinical Laboratory

- Founded in 2011
- CLIA certified in 2013
- CAP certified 2014
- Provided some of the world's first clinical studies for personalized cancer treatment
- Spun out from TGen in 2014, provides commercial access to personalized cancer treatment via genomic profiling of DNA from tumor and normal biospecimens
- Provides genomic testing for cancer centers across the US
- In 2018, began serving City of Hope (Duarte, CA) Oncologists and Patients
- Serves >70 U.S. cancer centers, hospitals, universities and laboratories

# Collaboration is a key market advantage

## The University of Melbourne

- Australia's peak research-intensive institution, ranked 32nd 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 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 specialising in cancer treatment in the US
- The University of Cambridge's UK Institute is a world leading cancer biotech centre

## GTG 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

# Intellectual property is our 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

# Scientific authority

## Dr. Richard Allman, Chief Scientific Officer

- Strong publication record in genetic epidemiology across multiple disease categories
- Collaboration for peer review and statistical validation

**BSc Microbiology, PhD Microbiology (Flow Cytometric Analysis of Bacteria)**
**Honorary Fellow, Centre for Epidemiology and Biostatistics, The University of Melbourne**

- Over 20 years of scientific and research experience
- Academic and commercial experience in research leadership, innovation management, and intellectual property strategy
- Academic career encompassed oncology research, drug development, and assay design, with a particular interest in the linkage between onco-genetic profile and treatment response

# Hainan Medical Pilot Zone

## GTG has established its Asian operations with the formation of Genetic Technologies HK and Hainan Aocheng Genetic Technologies

- Part of the Hainan Free Trade Zone Initiative
- Best-in-class medical care, physicians, treatments, technology and cutting-edge medical product development
- Hainan Free Trade Zone allows foreign companies to safely introduce IP and repatriate profits

## Chinese healthcare market valued at US$925B


*GTG Chairman and CEO, Dr Paul Kasian proudly accepted the formal documentation to establish Genetic Technologies' operations in Hainan, China.*

# GTG's approach aligns with Healthy China 2030

## Healthy China 2030 is the Chinese Central Government's comprehensive healthcare policy for 1.5 billion people

- Disease prevention is a means of controlling costs
- Chinese government can enforce compliance with preventive healthcare protocols

## GTG tests can be used to predict an individual's risk of developing disease

- Screening and other healthcare resources can be directed to people most at risk
- This allows for early intervention and less costly treatment
- Screening every woman for breast cancer may be too costly, but it may be cost-effective to screen those with a mid-to-high 5 year risk

# Next Steps in China

## Develop collaborative relationships

- Clinical validation
- Regulatory approval
- Commercial channels
- Laboratory testing

## Deliver the benefits of genetic screening

- Go-to-market plan for additional genetic screening tests
- Engagement with key opinion leaders
- Collaboration with Chinese research organisations

# Thank you

**Paul Kasian**
**Chairman and CEO**

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