



## **ASX ANNOUNCEMENT**

**13 September 2011**

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### **Investor presentation at Rodman & Renshaw Annual Global Investment Conference in New York**

Genetic Technologies Limited (ASX: GTG; NASDAQ: GENE) advises that the Company is attending the Rodman & Renshaw Annual Global Investment Conference in New York City and that its Chief Executive Officer, Dr. Paul MacLeman, is presenting the attached presentation at the Conference on Tuesday, 13 September 2011 (New York time).

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#### **FOR FURTHER INFORMATION PLEASE CONTACT**

Mr. Thomas G. Howitt  
Company Secretary

Genetic Technologies Limited  
Phone: +61 3 8412 7000



# **GENETIC TECHNOLOGIES LIMITED**

**(GENE:NASDAQ, GTG:ASX)**

*Rodman & Renshaw Healthcare Conference: September 2011*



# Forward Looking Statements

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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.

# Introduction

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- Currently in the 2<sup>nd</sup> year of a 5 year strategy to build a global cancer diagnostics business
- BREVAGen™ is the first product in this expansion
  - Launched USA June 2011
  - Breast cancer risk test – buccal (cheek) swab
  - Attractive gross margins and est. \$620m pa addressable US market
- 20 year old Australian genetic testing business has delivered sustaining cash flows and provides operational base for expansion – CLIA certification of Australia laboratory by CMS
- Growing licensing revenues from patent out-licensing
  - Non-coding DNA patent estate: Over 60 licensees/\$65m to date
  - 9 licenses granted FY2011 for \$13.7m
- Cash flow positive financial year 2010/11

# Established Genetic Testing Business



- Dominant market positions PacRim
- Globally accredited laboratory
- Experience producing & selling genetic tests
  - Oncology testing Australia, Asia & EU
  - Contracted provider to NSW Police Force for volume crime forensic testing
  - 50+% market share Aust/NZ paternity testing
  - Exclusive provider genetic testing most PacRim canine breed clubs
  - Leading contracted provider of paternity tests to lawyers, Dept of Immigration, Legal Aid & general public



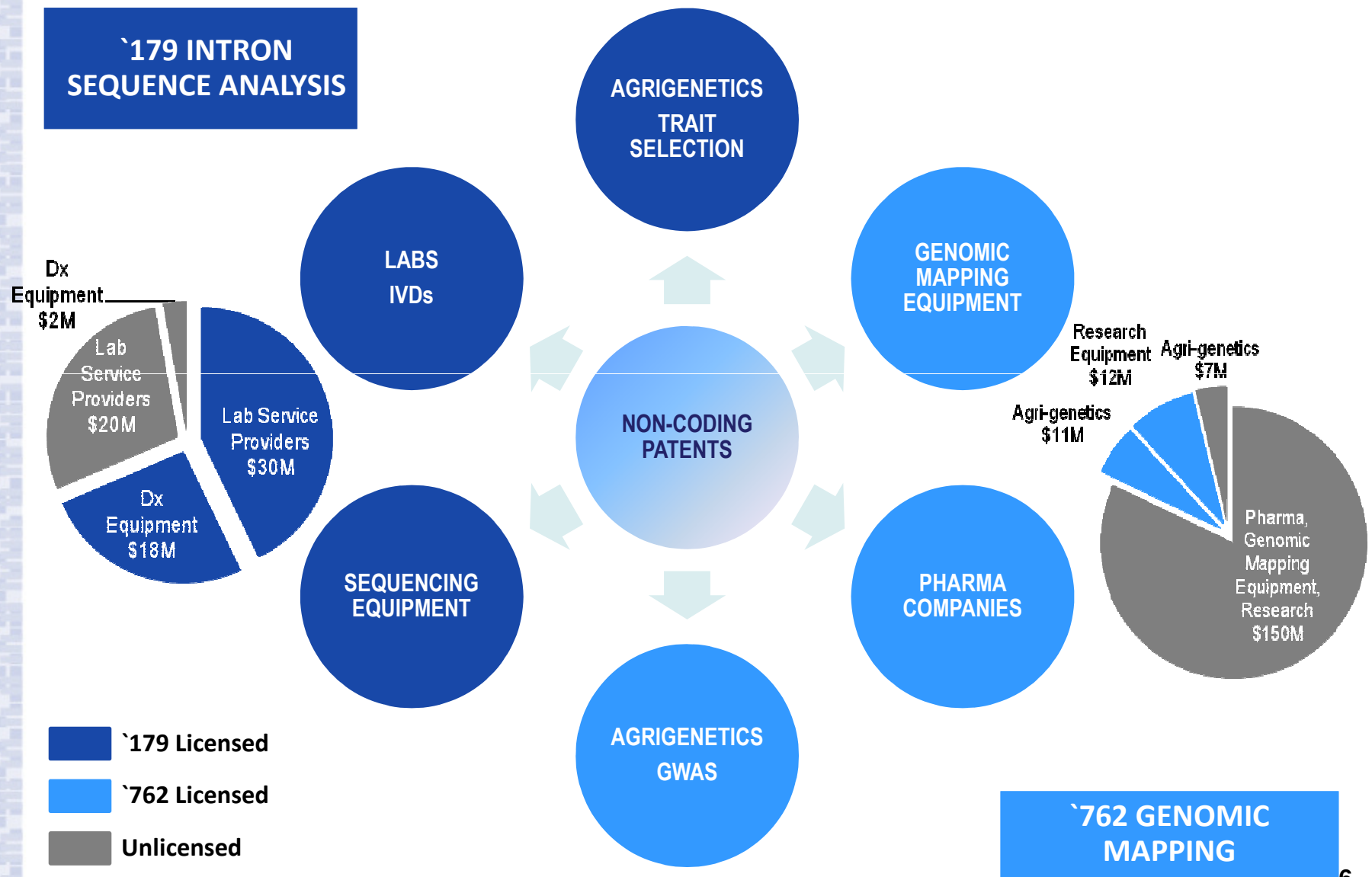
## Licensing: Non-Dilutive Funding Source

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- Non-coding DNA patent estate is one of GTG's core assets
  - \$65m+ licensing revenue received to date
  - 9 Licenses granted FY2011 to date for total \$14.2m
  - Contracted annuity stream of \$7m in total to 2015
- Foundational patent families protecting the use of non-coding DNA for genetic analysis
  - '179, "Intron Sequence Analysis"
  - '762, "Genomic Mapping"
  - '033, "Methods for Identifying Matched Groups"
  - '589, "Methods for Genomic Analysis"
  - '025, "Genetic Analysis Systems and Methods"
- Assertion strategy US (series of formal patent infringement suits)
- Single party negotiations EU & RoW

# Industry Scope and Available Markets



# Patent Assertion Program



- IP assertion program with off balance sheet funding
- Sheridan Ross in Denver driving legals
- 1<sup>st</sup> suit filed Feb 2010
  - All 9 parties settled prior to trial for total of over \$5 million
- 2<sup>nd</sup> suit filed Jan 2011
  - All but one party in settlement discussions
- 3<sup>rd</sup> suit with 10 parties filed May 2011
  - 1<sup>st</sup> party settled out within 4 weeks
- 4<sup>th</sup> suit in preparation



Pfizer Animal Health

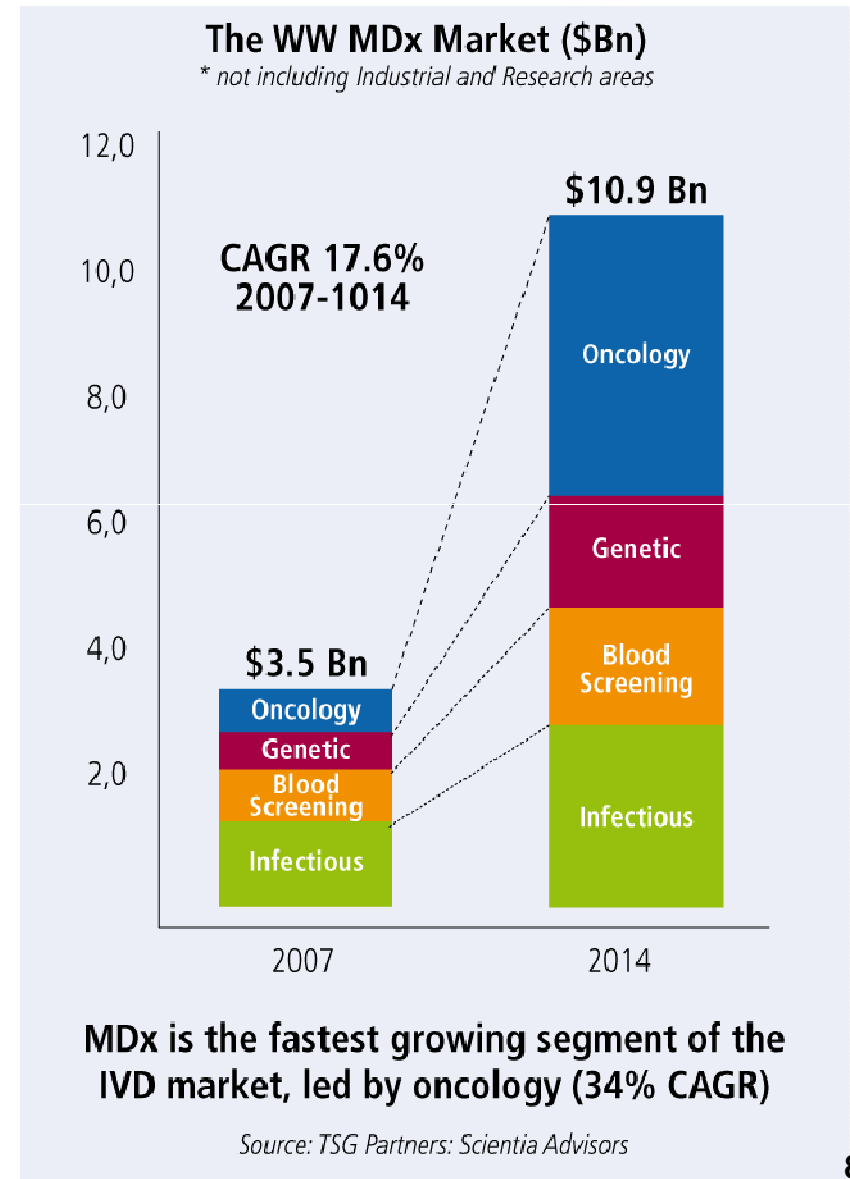


# Cancer Diagnostics Focus

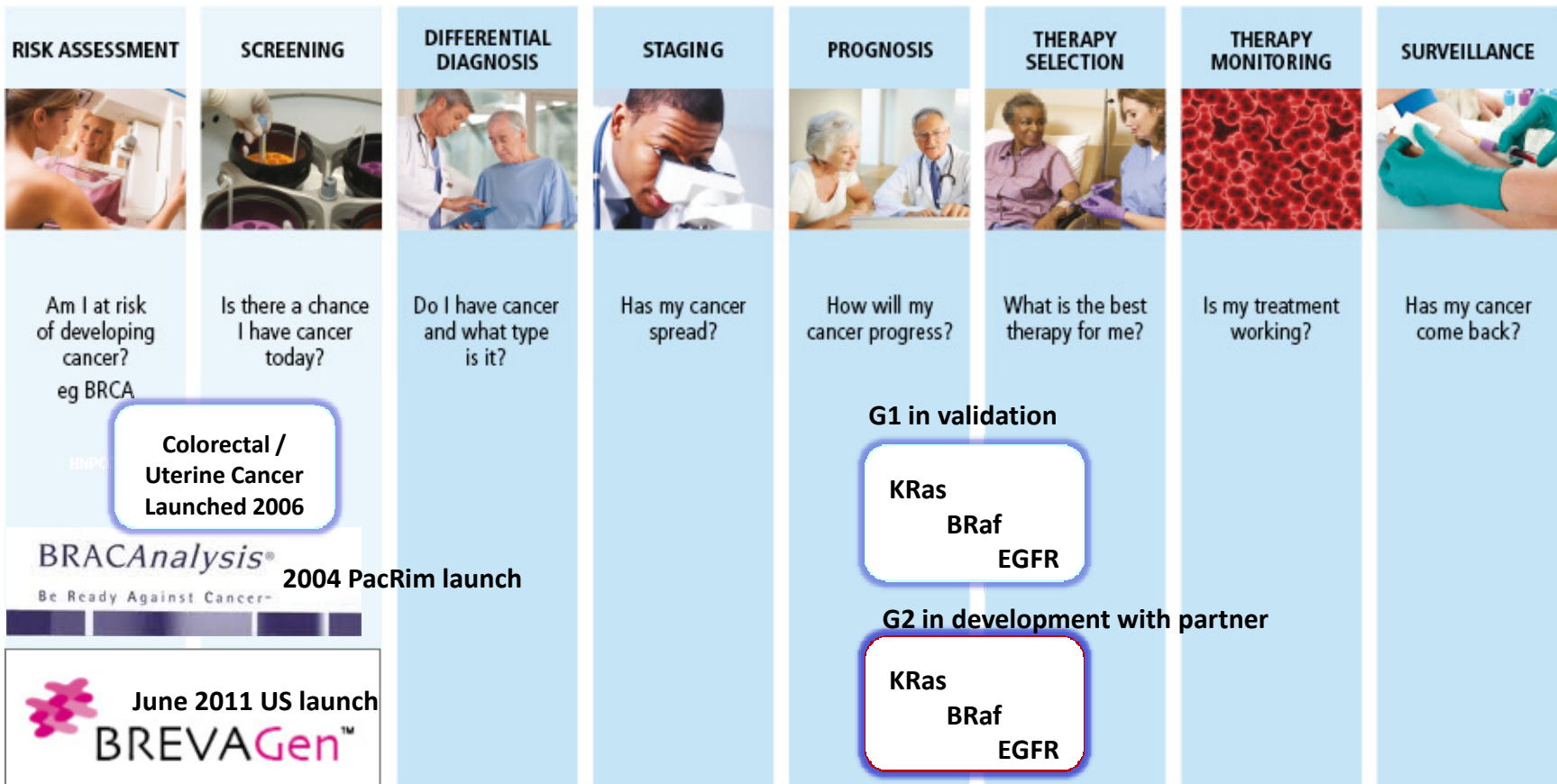


- New technologies driving personalized medicine & extending lives
- Molecular diagnosis of cancer is most attractive segment of diagnostics industry
- Focused market & efficient sales process
- Accelerating growth forecast next 4 years
- Global market exposure via BREVAGen™ & other new oncology products
- Builds on existing expertise in PacRim cancer Dx marketing

\* MDx = molecular diagnostics

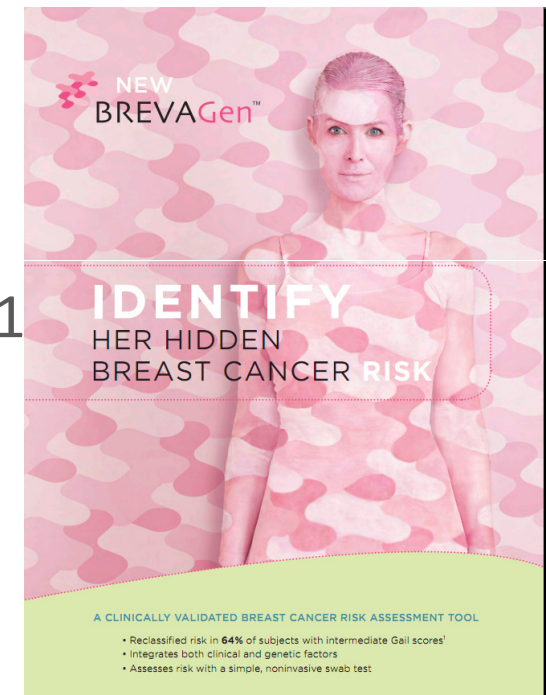


# Portfolio Strategy



- Developing a portfolio of tools across cancer management spectrum, focus
- Developing &/or acquiring products with global protection, application & scope

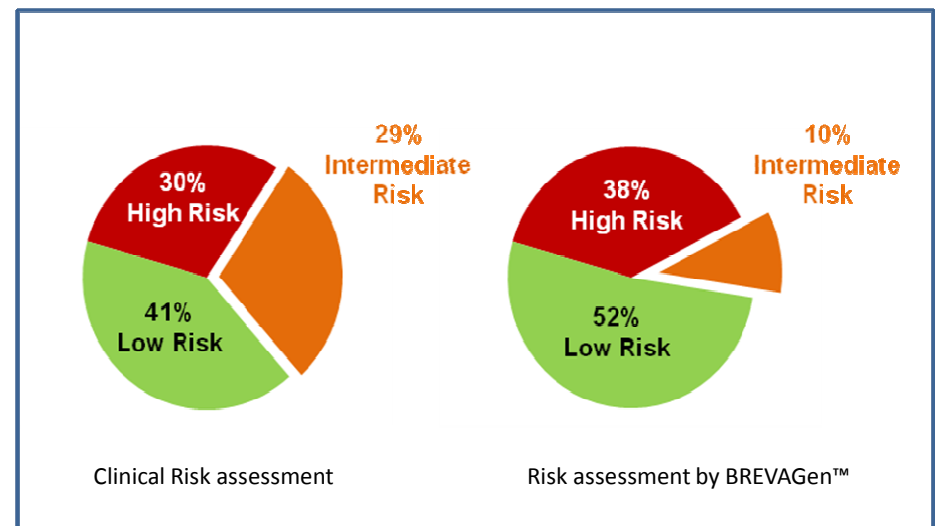
- Novel, validated test for non-familial breast cancer risk, published JNCI Oct2010
- US\$600m per annum US market opportunity
- Attractive gross margin - buccal swab
- Launched in 8 initial US territories June2011
- High profile Key Opinion Leaders involved
  - Experts at Stanford, Sloane-Kettering, Dana Farber
- Substantial global opportunity
- Reimbursement and regulatory strategy in place



## BREVAGen™: What does it Mean Clinically?



- BREVAGen™ classifies a woman's 5 year & lifetime risk of non-familial breast cancer, the commonest variety
- Test combines population risk factors with 7 genetic biomarkers (SNPs) to give an integrated, individual breast cancer risk assessment
- Supports existing American Society of Clinical Oncology (ASCO) & American Cancer Society (ACS) treatment guidelines
- Target market 1m intermediate risk biopsy patients, plus approx. 2-300k BRCA ineligible or negative patients



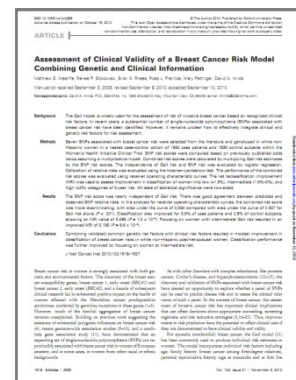
# BREVAgen™ Performance For Risk Prediction



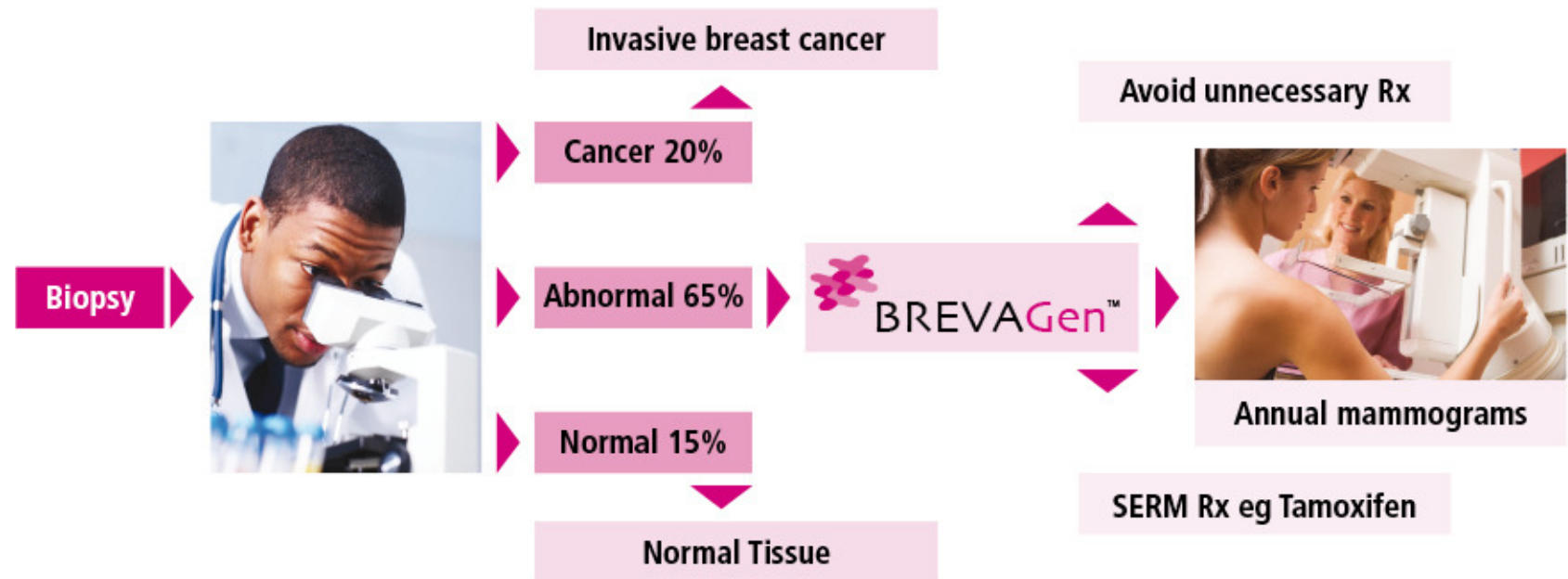
Mealiffe ME, et al., *Assessment of Clinical Validity of a Breast Cancer Risk Model Combining Genetic and Clinical Information*; (2010). **Journal of the National Cancer Institute** 102: 1-10. <sup>1</sup>.

| <b>BREVAgen™ risk reclassification results from 3,000 patient clinical validation study<sup>1</sup></b> |                                                                                                                                                                                                                          |
|---------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>33%</b>                                                                                              | Reclassified risk scores for 33% of patients and controls compared to the Gail score alone, reducing the intermediate risk category by 26%<br>–Risk classification improved with an NRI value of 0.085 ( $P \leq 0.05$ ) |
| <b>64%</b>                                                                                              | Reclassified 64% of all subjects with intermediate Gail scores<br>–Risk classification improved with an NRI value of 0.085 ( $P \leq 0.05$ )                                                                             |
| <b>32%</b>                                                                                              | Reclassified 32% of all subjects with previous breast biopsies<br>–Risk classification improved with an NRI value of 0.175 ( $P \leq 0.05$ )                                                                             |
| <b>ER+</b>                                                                                              | Significantly more predictive for ER-positive ( $P \leq 0.05$ ) than ER-negative tumors ( $P > 0.05$ )                                                                                                                   |

The Net Reclassification Index (NRI) was used to reclassify women into low (< 1.5%), intermediate (1.5% to 2.0%), and high (> 2%) categories of 5-year risk.



# BREVA Gen™ – Supports Existing ASCO & ACS Breast Cancer Management Guidelines



1.6m breast biopsy patients pa (US)  
65% or 1m patients at intermediate risk due abnormal pathology  
Preventive therapy can prevent 50-70% cancers if targeted via BREVA Gen™  
Analysis reported in ASCO poster 2010 backs cost effectiveness in this context

# Target Patient Groups



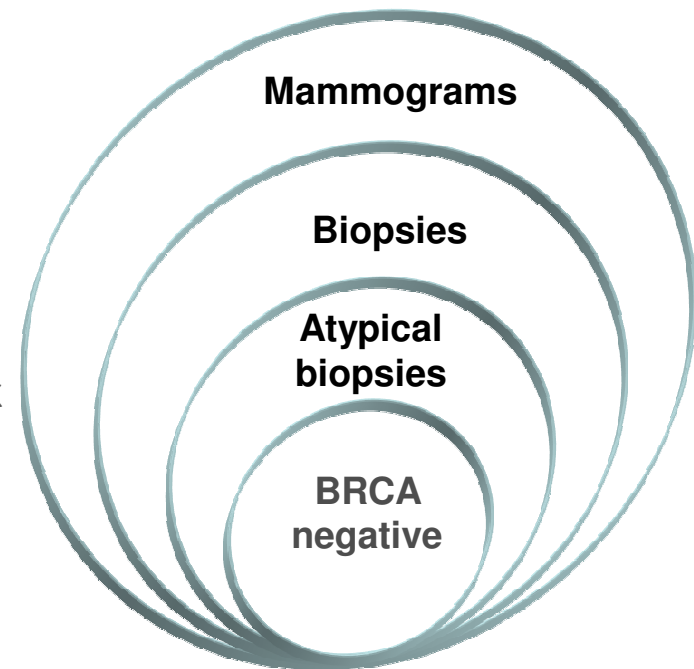
## Target market build

### Initial target markets

- 1,521 High Value MD/OBGYNs with high numbers of BRCA patient tests identified
- 80-90% of BRCA results are negative, plus other higher risk patients ,200-300k pa
- 1.6m breast biopsies in total pa
- 1m atypical biopsy patients pa
- 82,000 relevant MD population

### Later target market

- Women concerned with breast cancer risk over 35yrs of age
- 15.5m mammograms pa USA
- Next clinical trial to

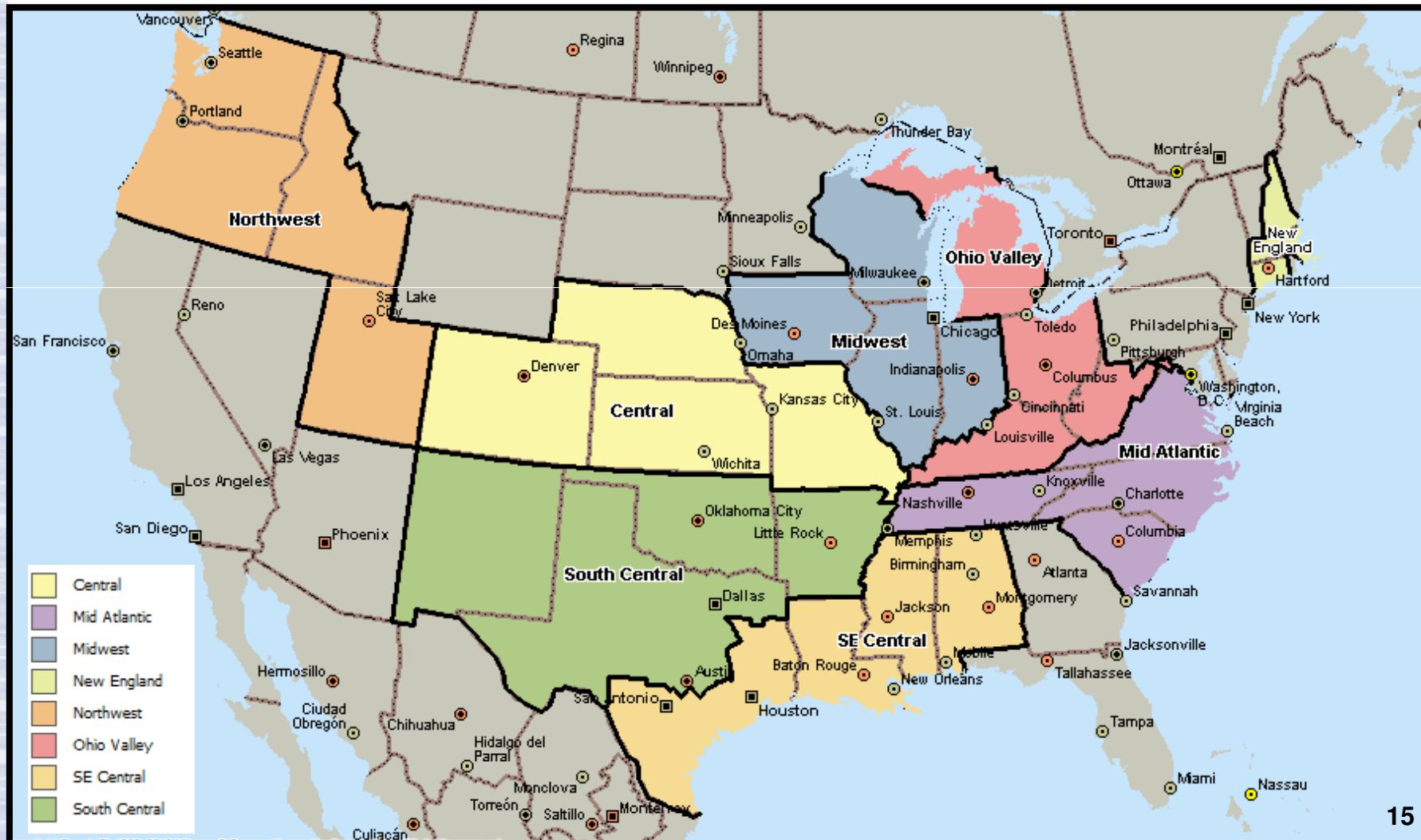


# National View of the 8 Initial Territories



Selected on the basis of:

- CLIA status - Reimbursement ease - Patient clustering



## BREVAGen™ Rest of World

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- Substantial additional opportunities exist in Europe and PacRim
- Some re-calibration of algorithm may be needed for some European populations
- Status of existing dossier would enable reasonably rapid CE marking
- Assessment of initial EU target markets and distributor candidates to commence H2 '11
- Potential UK distributor candidate identified
- PacRim regulatory status benign but reimbursement challenging

## Established Facilities



### **Genetic Technologies Limited Fitzroy, Vic, Australia**

Technical & corporate support and  
globally accredited sample processing.  
ISO, RCPA, NATA & CLIA certified.



### **Phenogen Sciences Inc Charlotte, North Carolina, USA**

Sales & marketing, customer support,  
reimbursement mgt  
and sample accessioning.



# BREVAGen™ Competitors

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- deCODE (Iceland)
  - Launched in October 2008 by deCODE Genetics, no validation
  - deCODE Breast Cancer test assesses risk based on 16 common SNPs, ordered only via MDs. Price = \$1,650
  - Emerged from Chapter 11 in April 2010 as a private company – no US presence since
- InterGenetics (Oklahoma City)
  - Breast cancer test is based on 22 SNPs, no validation
  - Limited sales and marketing presence
  - Self generated regulatory difficulties
- Other, largely direct to consumer
  - Navigenics
  - 23&Me
  - Knome

# Execution Capability & Monitoring



- Quantitative Strategic Risk Register allows monitoring, measurement and reporting of key success factors
  - Developed with assistance from Marsh Risk Consulting
- Items tracked and managed include:
  - KOL development
  - Medical marketing success factors
  - Licensing relationships management
  - Sales force development
  - Regulatory monitoring, planning and execution
  - Reimbursement planning and resourcing
  - Cash resourcing
  - Usual business continuity risks also monitored

# Management Expertise



Tom Howitt,  
Chief Finance Officer  
20 years of expertise in  
public Co. governance  
and capital raising



Alison Mew  
Chief Operating Officer  
20 years of expertise  
cGMP manufacturing  
and operations across 3  
continents



Dr. Paul MacLeman  
CEO  
International diagnostics,  
therapeutics  
commercialization and  
investment banking  
experience and expertise



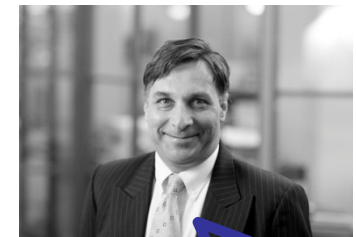
Dr. David Sparling  
V.P Corporate  
Development  
Specialist in Intellectual  
Property and M&A in  
pharmaceutical and  
diagnostic sectors



Greg McPherson  
V.P Sales & Marketing  
20 years international  
experience in  
establishing international  
businesses and  
territories

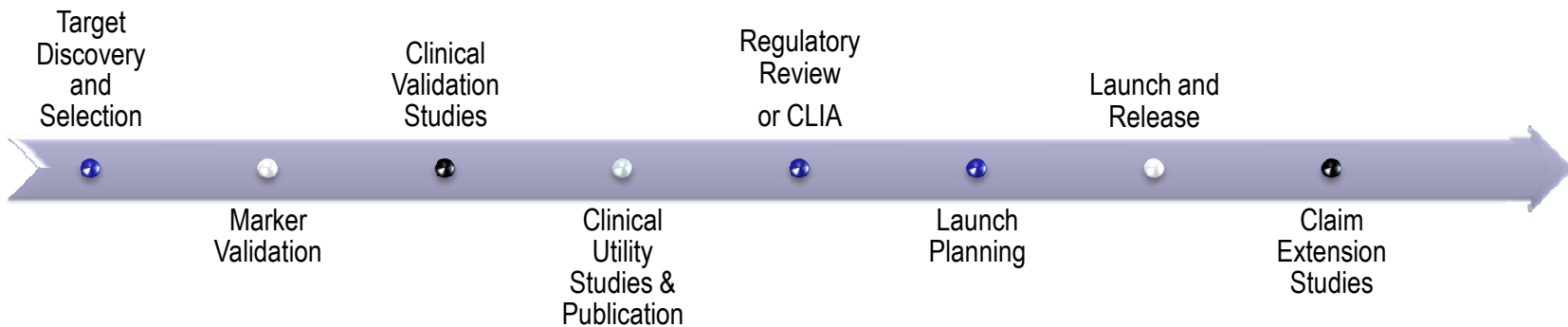


Lewis Stuart  
General Manager, USA  
Twice worked to drive start  
up companies to revenues  
in excess of \$300m and  
>\$1b trade sales



Ivan Jasenko,  
Regulatory & Quality  
Manager  
Extensive international  
cGMP regulatory experience  
incl. PMA and 510k filings

# Product Portfolio



BRCA/HNPCC/SCN1A (EU/PacRim)

BREVAGEN™

KRAS/BRAF/EGFR (FPFE)

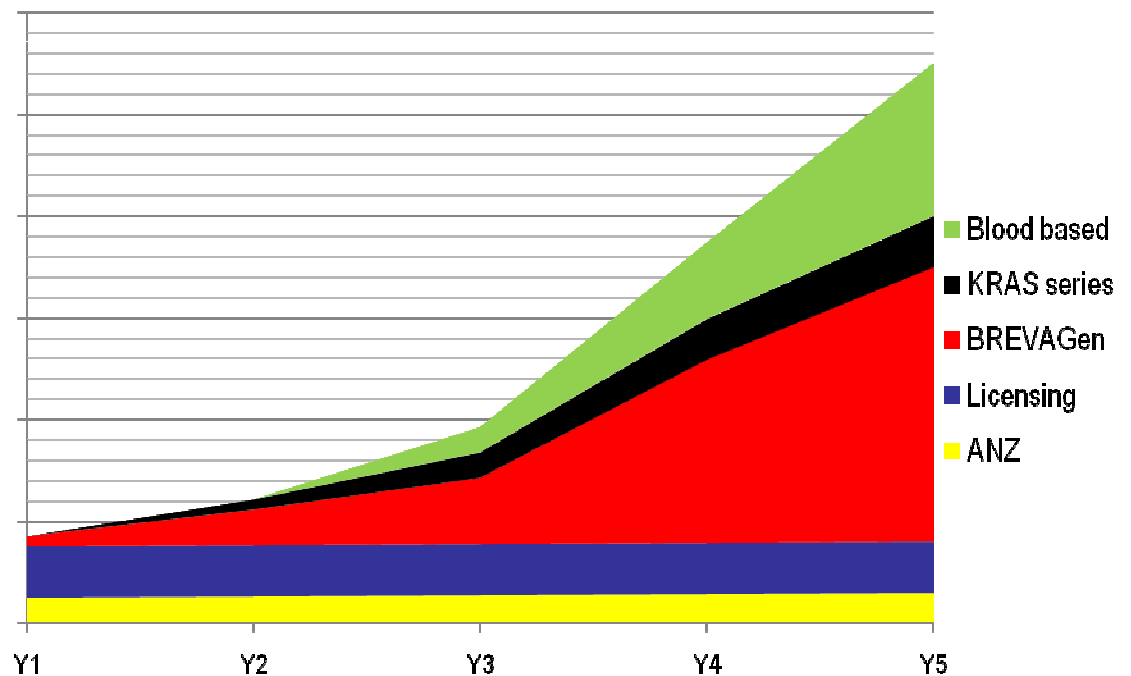
Partnered Companion Theranostic

Theranostic markers (circulating)

# Portfolio Revenue Growth



- BREVAGen™ the first global product in the cancer diagnostics strategy
- Followed by introduction of generic theranostic markers late Y2
- Y3 introduction of blood based G2 products
- Companion Dx and M&A in addition to this
- Collaboration with multinational pharma



# Growth Strategy



- GTG acquired, validated and integrated BREVAGen™ as a near to market asset 2010
- MDx assets are currently cheaper to buy than to develop
- Actively assessing new product acquisitions
- Seeking:
  - On or close to market assets
  - Similar sales channels and marketing synergies to GTG's existing franchise: women's health, oncology
  - Nucleic acid, proteomic or immunohistochem platforms
  - Global rights
- Also seeking to partner/divest two non-core programs
  - RareCollect™
  - ImmunAid™

# Financial Snapshot June 2011



## Financials (12 months to Jun30)

| (AUD millions)      | <u>2011</u> | <u>2010</u> |
|---------------------|-------------|-------------|
| Revenue             | 18.3        | 8.7         |
| Operations*         | 4.6         | 4.9         |
| Licensing           | 13.7        | 3.8         |
| Net income / (loss) | 0.9         | (9.4)       |
| Cash ‡              | 5.1         | 3.3         |

‡ Placement AUD12.7m July 11

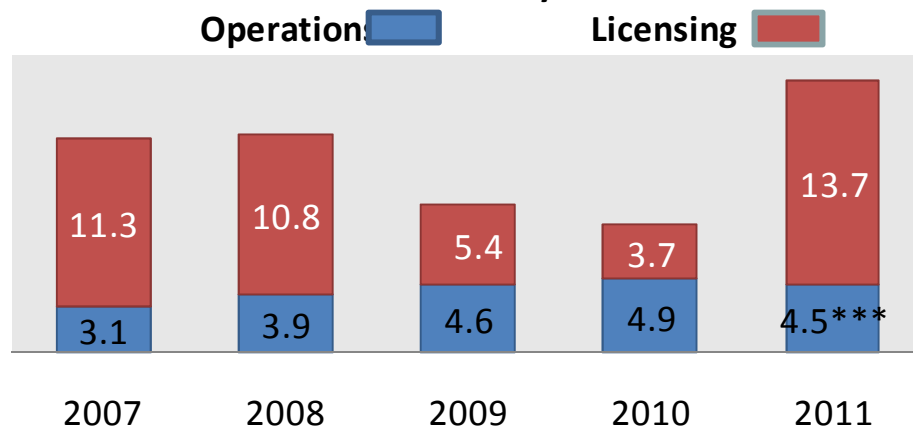
\*/\*\*\* Following divestment \$750k revenues

\*\* Employee options only

## Share Register

|                                   |        |
|-----------------------------------|--------|
| Shares outstanding                | 464.6m |
| Top 20 shareholders               | 76%    |
| Total shareholders                | 2,850  |
| Options outstanding **            | 19.7m  |
| Market cap (22 <sup>nd</sup> Aug) | AUD79m |

## Sales A\$m – 5 years



c Technologies Ltd



# Summary

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- GTG launched world's first validated test for non-familial breast cancer risk Jun11
  - BREVAGen™ has attractive CoGS & rapid payback
  - Target market is global, characterized & large
  - US sales, marketing & reimbursement infrastructure established
- GTG has a sound base of reliable, growing operational & licensing revenue streams
  - Cash flow positive and profitable 2011
- Clear track record in generating substantial ongoing licensing revenues
- Stable, reliable business with clear strategy for sustained growth and substantial upside potential

# Contact Details

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**Dr Paul D R MacLeman**  
**CEO Genetic Technologies Limited**  
**Phone**                   **+61 3 8412 7000**  
**Email**                   **info@gtglabs.com**

