



# Corporate Presentation



May 2014

# 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.

# Corporate Overview

- Revenue-generating global diagnostics business focused on women's health
- Lead product is breast cancer risk test BREVAGen™ for non-familial (sporadic) breast cancer
  - Launched mid-2011 and now approved and available in all 50 U.S. states
  - U.S. CLIA approved and CE Mark awarded
- Headquartered in Melbourne, Australia
  - Leveraging over 20 years of experience as the region's largest genetic testing business
  - Globally certified laboratory (CLIA, ISO, RCPA, NATA)
  - Sustainable cash flow provides operational base for new asset expansion
- IP out-licensing program generates recurring revenue stream
  - Approx. 77 licenses covering "non-coding DNA" granted to date, generating >\$73 million in revenue
  - Protected by extensive patent portfolio in 24 countries worldwide
- U.S. subsidiary, Phenogen Sciences Inc., focused on BREVAGen sales and marketing
- Dual-listed on NASDAQ (GENE) and ASX (GTG)

# Phenogen Sciences Inc.

- Established in 2010 to serve as platform for U.S. expansion within women's health
  - Headquartered in Charlotte, North Carolina
  - Manages U.S. sales and marketing of BREVAGen
- BREVAGen acquired from Perlegen Sciences Inc. in 2010 as a blood-based test
  - Test adapted by Phenogen into buccal (cheek) swab used today to improve patient compliance, efficiency and cost effectiveness
- BREVAGen growth and broader U.S. business development supported by legacy genetic testing business and ongoing IP out-licensing program
  - Enables potential for related MDx acquisitions to leverage established sales infrastructure
- Mark Ostrowski, U.S.-based SVP, Sales and Marketing, appointed in September 2012
  - 11 years at Myriad Genetics, including Head of Sales Operations

# Established Infrastructure



Genetic Technologies Limited  
Melbourne, Victoria, Australia

Technical and corporate support with laboratory globally certified to ISO, RCPA, NATA and CLIA

Phenogen Sciences Inc.  
Charlotte, North Carolina, U.S.

Sales and marketing, customer support, reimbursement management and sample accessioning to Laboratory Information Management System in Australia



# Sales Mix by Business Unit

- U.S. Operations
  - BREVAGen™ revenue
    - Historically accounted for on a cash basis – to move to accruals basis FY 2014
    - Claims received from private insurers
    - Patient Protection Program provides agreed lower limit for (patient) revenue per test
- Australian Operations
  - Heritage businesses (Asia Pacific) includes Medical, Parentage, Canine testing
    - Annual revenue: \$3 million - \$4 million
    - Mature businesses with limited scope for growth
  - Out-licensing
    - Variable, but significant, annual revenue: \$2.5 million to \$13.7 million over past 5 years
    - Long-term annual average revenue in excess of \$6.5 million
    - \$4.8 million in FY 2013
    - Numerous potential licensees (some with large infringement) being pursued

# BREVAGen™

# What is BREVAGen™?

- BREVAGen is a simple swab-based test that can help determine a woman's risk of developing breast cancer
- Genetic risk is combined with clinical risk from the Breast Cancer Risk Assessment Tool (BCRAT) to provide an integrated risk score
- Molecular panel of 7 SNPs (single nucleotide polymorphisms) identified from the Human Genome Project
- Each SNP is independently associated with estrogen receptor positive (ER+) sporadic breast cancer
  - Over 75% of all Sporadic Breast Cancer is Estrogen Receptor Positive
- Found in 25% to 50% of women, these SNPs are high frequency/low penetrance alleles
- First test of its kind to be clinically validated to assess both five-year and lifetime risk for sporadic, hormone-dependent breast cancer
- Validated and CLIA-approved for use in Caucasian women of European descent, aged  $\geq 35$

# Scientific Support for BREVAGen™

Mealiffe ME, *et al.* (2010). J Natl Cancer Inst. 102(21): 1618-1627

Assessment of clinical validity of a breast cancer risk model combining genetic and clinical information

- *Confirms the validity of combining SNP genotypes with the Gail model and demonstrates the utility of reclassification analysis for predictive risk tests.*

Comen E, *et al.* (2011). Breast Cancer Res Treat. 127: 479-487

Discriminatory accuracy and potential clinical utility of genomic profiling for breast cancer risk in BRCA-negative women

- *Provides independent confirmation of the validity of combining SNP genotypes with the Gail model. Demonstrates the clinical utility of improved risk assessment for guiding MRI screening and Tamoxifen chemoprevention.*

Dite GS, *et al.* (2013). Breast Cancer Res Treat. 139(3): 887-896

Using SNP genotypes to improve the discrimination of a simple breast cancer risk prediction model

- *Extends reclassification of breast cancer risk using SNP genotypes to a wider population age group.*

Folse H, *et al.* (2013). Cancer Prev Res. 6(12):1328-36

Cost-effectiveness of a genetic test for breast cancer risk

- *Simulated clinical trial demonstrates that use of BREVAGen™ to recommend MRI screening is most cost-effective for women with a lifetime risk between 16% and 28%. Importantly, this strategy is predicted to reduce breast cancer deaths by 2.66% (relative to Gail alone).*

Green, *et al.* (2014). Applied Health Econ Health Policy. 12(2): 203-217

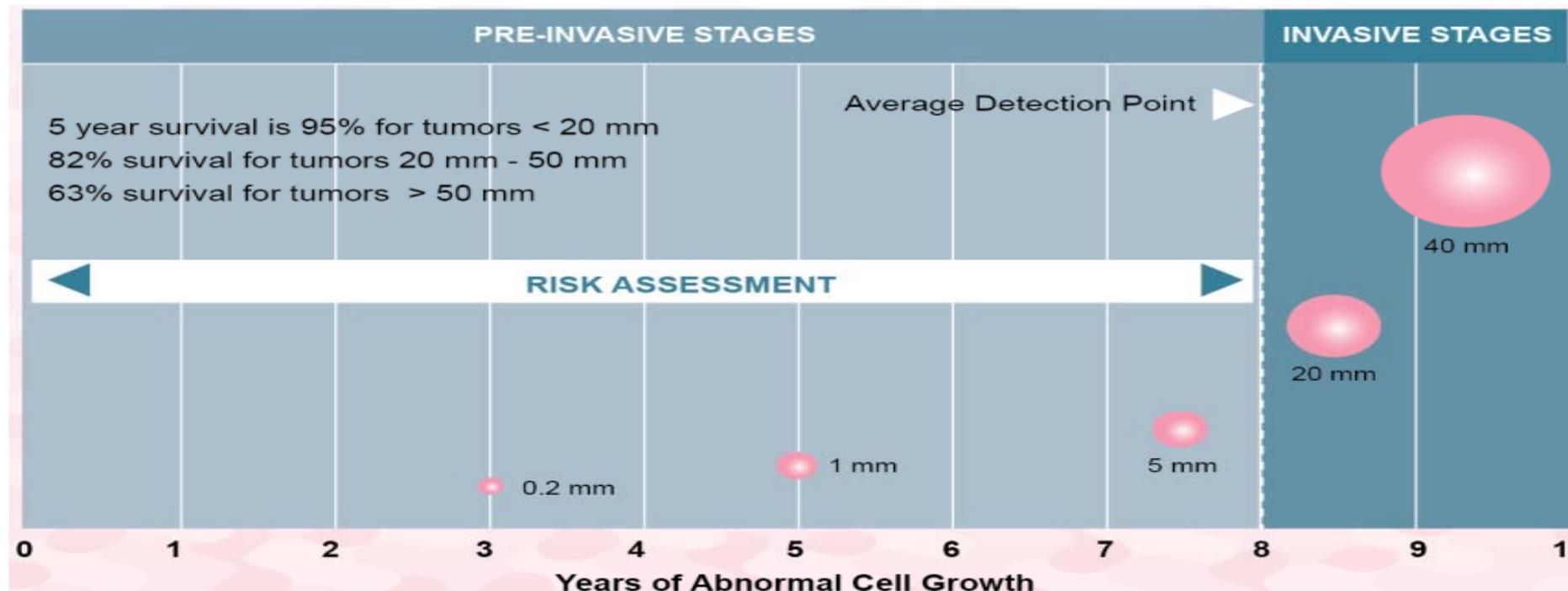
Economic Evaluation of Using a Genetic Test to Direct Breast Cancer Chemoprevention in White Women with a Previous Breast Biopsy.

- *Simulated clinical trial demonstrates BREVAGen is most cost-effective for women with a pre-test breast cancer t-year risk of 1.2 – 1.66%. Results demonstrated combining genetic susceptibility data with current breast cancer risk models used to guide chemoprevention recommendations improves clinical outcomes and is cost effective.*

# Breast Cancer Risk: Early Detection Is Key

- 1 U.S. woman in 8 will develop breast cancer in her lifetime
- 39,500 of these women will die each year
- HOWEVER, with early detection, >95% of these women can survive \*

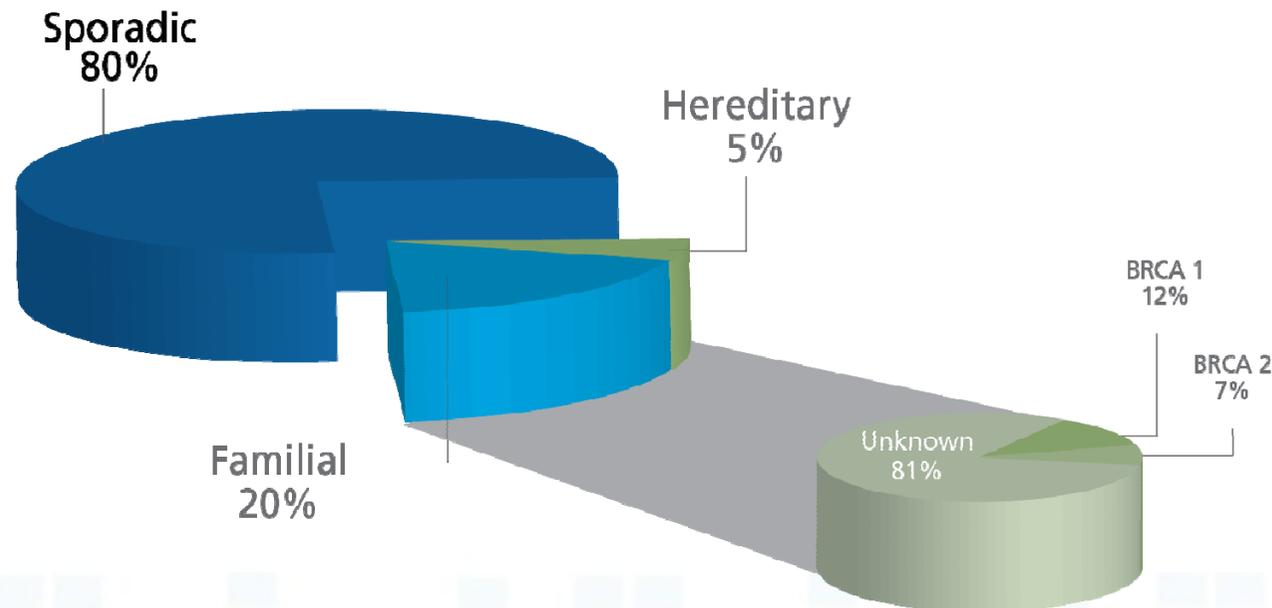
## Breast Cancer develops before it is detected



\* <http://www.cancer.org/cancer/breastcancer/detailedguide/breast-cancer-key-statistics>

# Familial vs. Sporadic Breast Cancer

- A total of 235,000 breast cancer cases are diagnosed each year in the U.S.
- 80% of breast cancer is “sporadic” (meaning no strong family history)
  - An estimated 188,000 sporadic cases are reported each year
- BREVAGen™ focuses exclusively on risk for sporadic breast cancer
  - Women who are BRCA negative, with no/limited family history, who may have an elevated clinical risk



# BREVA Gen™ Differentiated Integrated Risk Score



**BREVA Gen™**

GET A CLEARER PICTURE  
*of breast cancer risk*

A validated breast cancer predictive test

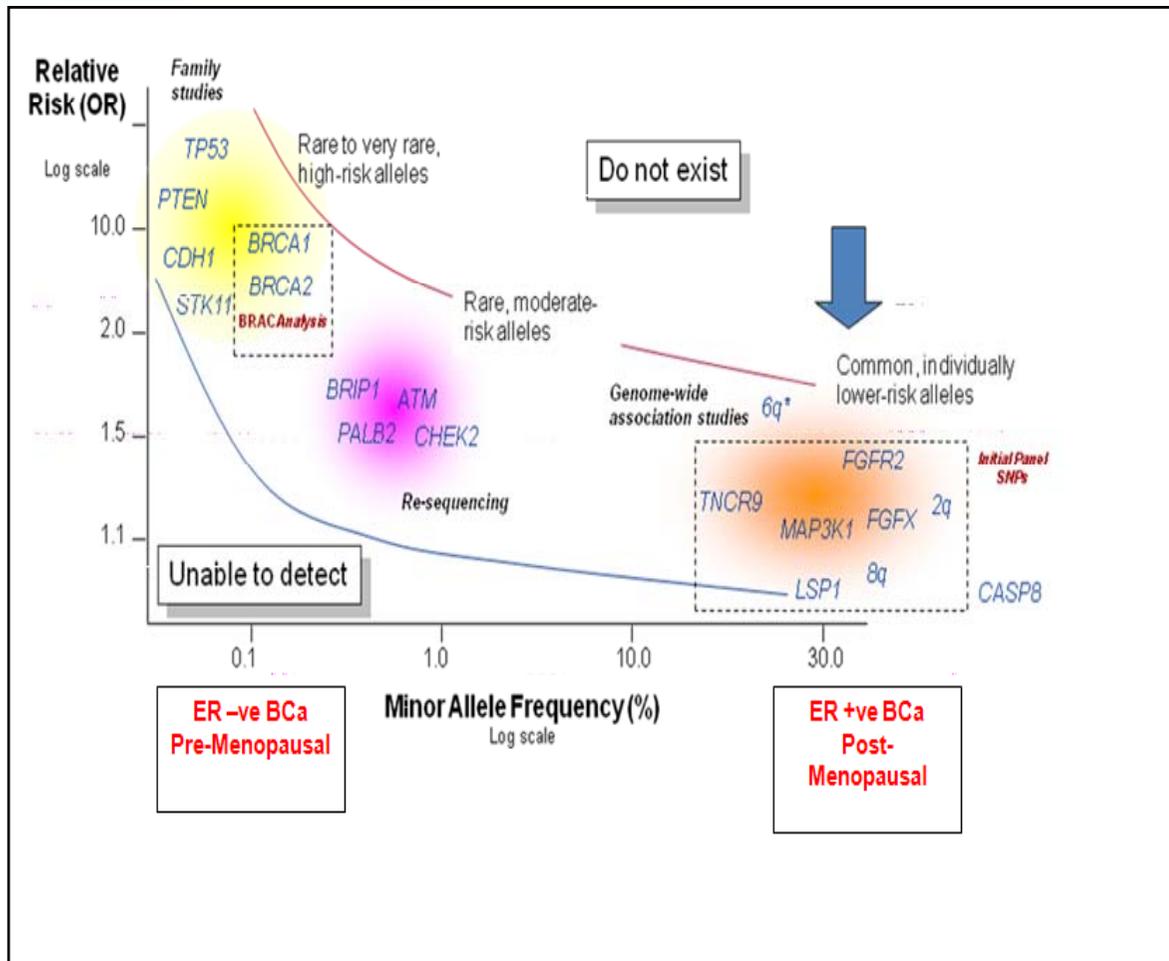
- Identifies sporadic breast cancer risk, integrating clinical and genetic factors
- Enables the development of a Breast Health Plan, matching patient risk profile to a preventive/surveillance care path
- Uses a simple, non-invasive swab test

- BREVA Gen™ provides both a five-year and lifetime percentage risk of developing sporadic breast cancer
- Allows physicians to recommend a personalized 'Breast Health Plan' outlining better surveillance strategies and proactive changes, tailored to each patient's lifestyle and health status
- Provides medical management options based on independent guidelines from the American Cancer Society and ASCO (last updated 2009)

# BCRAT / Traditional GAIL Score

- Traditionally, a patient's risk of sporadic breast cancer has been identified by using clinical factors alone
- Historically known as the GAIL score, Breast Cancer Risk Assessment Tool (BCRAT) measures a woman's hormonal and reproductive risk factors, including:
  - Pregnancy history
  - Current age
  - Age at menarche
  - Age at menopause
  - Race/ethnicity

# Cumulative Impact of Common, Low Risk Alleles



- Low-risk alleles are predictive of estrogen receptor positive (ER+) tumor types and account for the majority breast cancer incidence
- More than 80% of breast cancer incidence is sporadic
- 75% of sporadic breast cancer is ER+

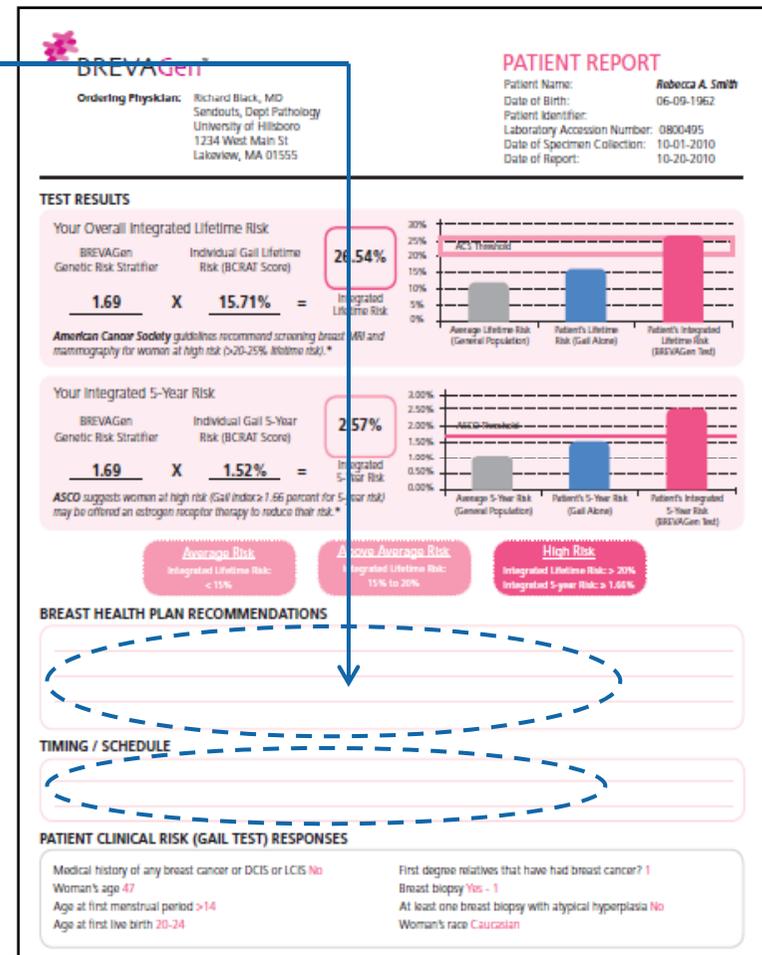
# BREVAGen™'s Clinical Difference

- Early detection of breast cancer is the key to successfully fighting it

  - BREVAGen enables more accurate selection of patients for MRI screening
  - Only 53% of women maintain regular mammographic screening \*
  - BREVAGen™ helps solve the over/under use of the mammography debate by tailoring the right schedule for the right risk profile
- USPSTF (April 2013) recommends the use of tamoxifen / raloxifene in high risk women

  - BREVAGen provides a more accurate five-year risk assessment
- Recent legislation requires MD to notify patient of dense breast tissue following mammography

  - Patients identified as having dense breast tissue are recommended to discuss risk assessment options



# Summary - The Benefits of BREVA Gen™

1. Improved Health Outcomes
2. Improved Cost Effectiveness

*when intervention and surveillance are appropriately applied to women at higher risk*

# BREVA Gen™ Competitive Landscape

There is limited, if any, real competition to BREVA Gen, which includes:

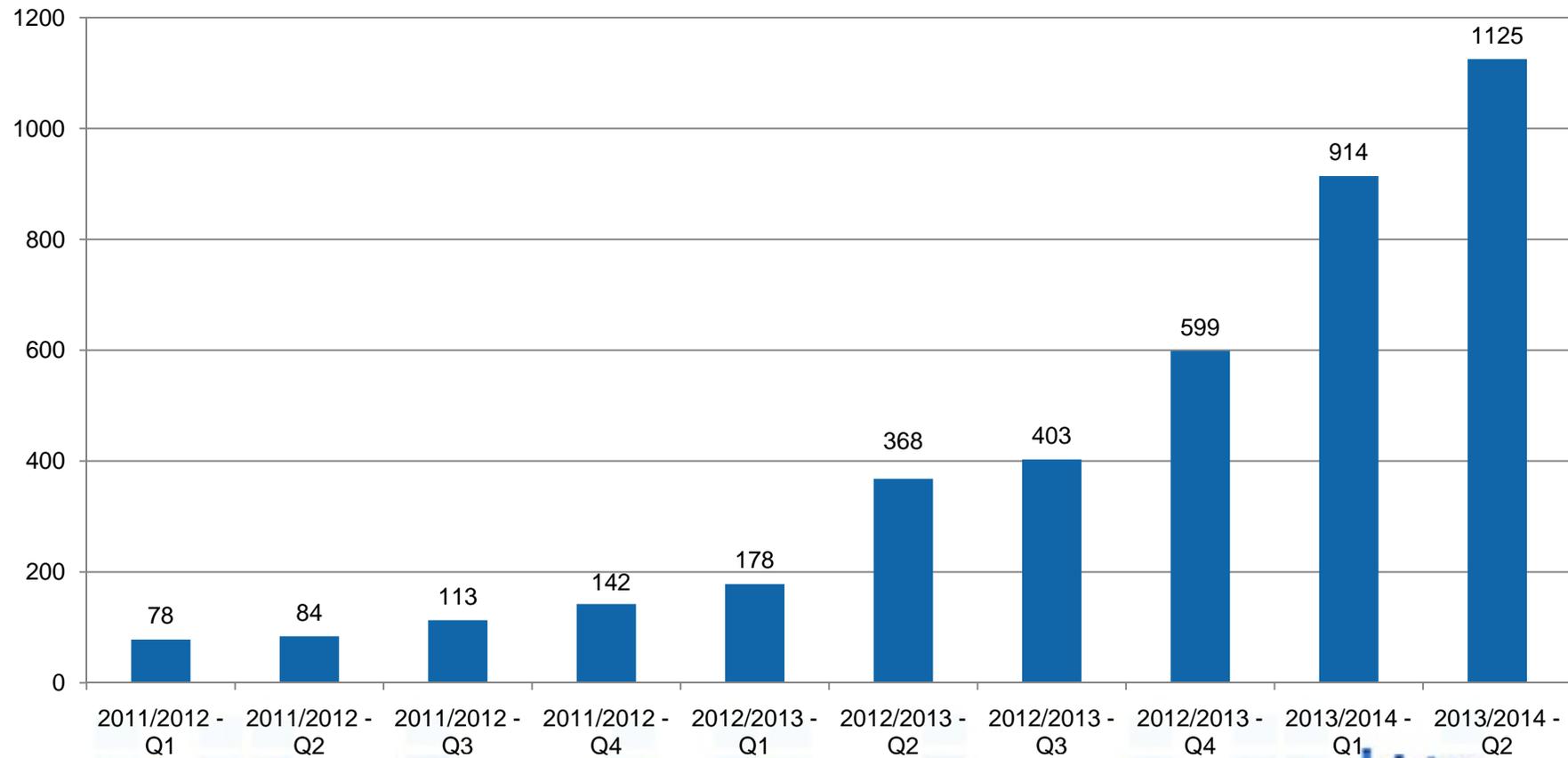
- deCODE (Iceland)
  - Launched in October 2008 by deCODE Genetics, but with no validation
  - deCODE Breast Cancer test assesses risk based on 16 common SNPs, ordered only via MDs
  - Emerged from Chapter 11 in April 2010 as a private company – purchased by Amgen in December 2012, primarily for companion diagnostics assets
- InterGenetics (Oklahoma City)
  - Breast cancer test is based on 22 SNPs, but with no relevant validation
  - Limited sales and marketing presence
  - Self generated regulatory difficulties
- Other (largely direct to consumer)
  - Navigenics (FDA warning letter received and test subsequently withdrawn from the Market)
  - 23&Me (FDA warning letter received and test subsequently withdrawn from the Market)
  - Knome

# U.S. Market - Targeted Patient Profiles for BREVA Gen™

- Women meeting the criteria below may be appropriate candidates for BREVA Gen:
  - Age  $\geq$  35 years
  - Caucasian (based on current test)
  - Gail-model appropriate
  - Other clinical risk factors
- BREVA Gen is appropriate for women who return a negative breast biopsy result  
= 1.3 million each year
- BREVA Gen is most appropriate, and most cost effective, for women of above average clinical lifetime risk  
(10.3% of women are in this category at age 50)  
= 7.5 million women each year (including those with a negative biopsy result)

# BREVA Gen™ Performance

## BREVA Gen Samples Received By quarter (launch to end of December 2013)



# BREVAGen™ Market Progress

- BREVAGen now available in all 50 U.S. states
  - Samples received from 18, high population density territories
  - Targeting OBGYNs and breast centers
    - Patients with above average clinical risk (7.5 million women at age 50 annually)
    - Patients with negative breast biopsies (estimated at 1.3 million annually)
- 23 Key Opinion Leaders (KOLs) act as BREVAGen Ambassadors to:
  - Highlight the utility and value of BREVAGen in the clinical setting
  - Provide templates for clinic adoption, patient selection and logistics
  - Drive increased adoption of the BREVAGen test
- High prescribing users and KOLs on TV aim to:
  - Introduce BREVAGen to the general public
  - Integrate PR with new speakers in the various sales territories

# Current Locations of U.S. Sales Force



## Western Region (7 reps)

- Seattle
- Dallas
- Houston
- Chicago
- Southern California
- Missouri/Kansas
- Northern California / Nevada

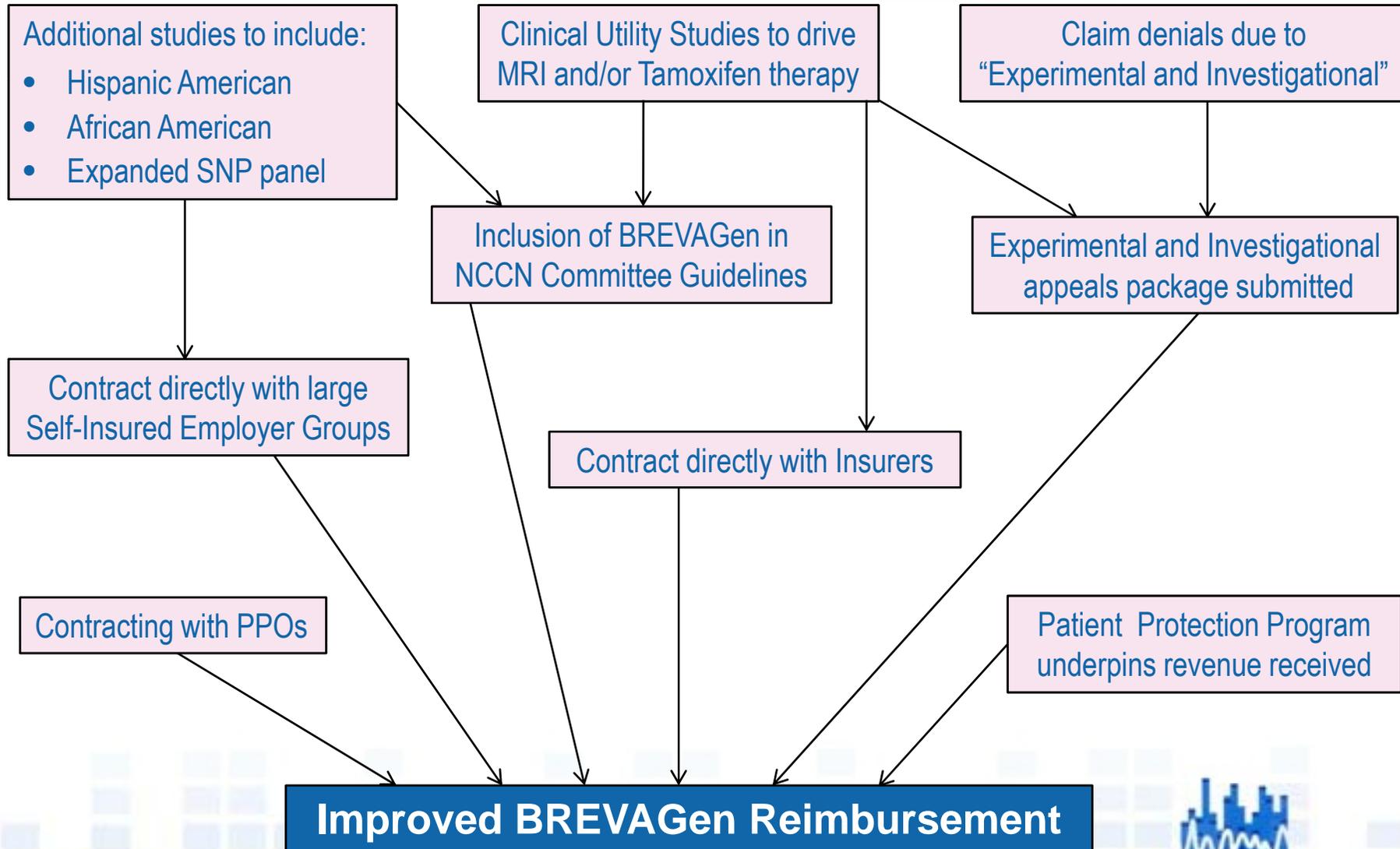
## Eastern Region (8 reps)

- New England
- Northeast
- Ohio / Michigan
- DC / MD / VA
- Florida
- New Jersey
- New York City
- KY / TN / IN

# Reimbursement Profile

- In January 2013, there were material changes to the reimbursement process:
  - Coding changes impacted all genetic / MDx testing in the U.S.
  - Transition from “code stack” to “miscellaneous” CPT code
  - Denials and follow-on appeals have since increased, but with strong PPO contracting and increased list price, average reimbursement for closed cases has increased by >50%
  - As sample numbers received increase, proportionately more cases are awaiting reimbursement
- Planning underway for clinical utility and supporting study. Will facilitate direct contracting with Insurers leading to faster and better payment outcomes.
- Expanding the application of BREVAGen to additional ethnicities, will allow direct contracting with private payers.

# Reimbursement Improvement – Actions Being Taken



# BREVAGen™ Product Development

BREVAGen 1.0: 7-SNP assay, available to Caucasians only

- Caucasian population in the U.S. is 62%
- Recent advances in genetics need to be included

Plan to develop and launch BREVAGen 2.0 by third quarter of calendar 2014

- Expanded panel for Caucasian women
- Risk assessment panel for African-American women
- Risk assessment panel for Hispanic American women
- Collaborators and protocols have been designed
- Initial case control study to include additional ethnicities and more SNPs is now underway



# Corporate Summary

# Management

- **Alison J. Mew, Chief Executive Officer**
  - Appointed CEO in December 2012
  - Background in operations management in the biopharmaceutical industry in Australia and overseas, covering animal and human health
  - Over 13 years with CSL Ltd. in senior positions
- **Richard Allman, PhD, Scientific Director**
  - Over 20 years of scientific and research experience in the UK and Australia
  - Most recently responsible for providing scientific and technical guidance for the launch of the BREVAGen™ risk assessment test to the US market and managing associated research programs
  - Academic career encompassed oncology research, drug development and assay design, with a particular interest in the linkage between onco-genetic profile and treatment response
- **Mark J. Ostrowski, Senior Vice President Sales and Marketing – Phenogen Sciences Inc.**
  - Appointed Senior Vice President Sales and Marketing – Phenogen Sciences Inc. in September 2012
  - More than 20 years of sales and marketing experience in molecular diagnostics (including Director of Sales Operations at Myriad Genetics (NASDAQ: MYGN) and Director of Managed Care Services at DIANON Systems)
  - Academic tenure in the specialized molecular diagnostics space and led successful commercialization and clinical adoption and reimbursement of now standard-of-care clinical molecular diagnostic assays used in the diagnosis and management of cancer

# Licensing Overview

- Seven new licenses granted during the 2013 financial year, totalling 77 to date
- More than \$73 million in gross revenues generated from licensing to date
- U.S. assertion program continues in earnest, with 10 cases of infringement underway, including three against Big Pharma (Pfizer, GSK and BMS)
- New assertion cases focusing on “762” mapping patent to extend the life of the licensing program
- European targets being independently pursued by Genetic Technologies
- Third re-exam of “179” patent successfully defended
- Goal to continue to deliver valuable non-dilutive funding to the Company

# Financial Snapshot

## Financials (9 months to March 31)

| (AUD millions)      | <u>2014</u> | <u>2013</u> |
|---------------------|-------------|-------------|
| Revenue / gains     | 5.0         | 6.4         |
| Operations          | 3.1         | 2.5         |
| Licensing           | 0.6         | 3.6         |
| Net profit / (loss) | (7.6)       | (6.4)       |
| Cash                | 5.0         | 3.1         |

## Share Register

|   |                |
|---|----------------|
| Shares outstanding                      | 588.8 million  |
| ADRs (@30:1 ratio)                      | 19.6 million   |
| Top 20 shareholders                     | 71.2%          |
| Total shareholders                      | 2,889          |
| Options outstanding<br>(employees only) | 10.8 million   |
| Market cap (@ \$0.05)                   | AUD 29 million |

