

## GENETIC TECHNOLOGIES, LTD. (NASDAQ: GENE)

### BREVAGen Off To Healthy Start as Reimbursement Coverage Continues to Build; Licensing Activity Likely to Pick Up in 2H12. 1H12 Financials In Line With Forecast.

**INVESTMENT RATING** BUY  
*Prior rating*

Price Target US\$7.50  
*Prior Target*

Price (2/27/12 Intraday) \$3.99  
52 Week Range(\$US) \$1.50 - \$10.75  
Shares Outstanding (ADR) 13.8 MM  
Market Cap. (\$US) \$62.6 MM  
Cash (12/31/11) \$12.6 MM

**FISCAL YEAR END** June

**REVENUE (MM's):**

	Current	Prior
2013E	\$21.0	\$21.2
2012E	\$12.1	\$12.5
2011A	\$18.3	

**EPS (F.D.):**

	Current	Prior	P/E
2013E	\$0.07	\$0.08	NA
2012E	(\$0.28)	(\$0.23)	NA
2011A	\$0.07		NA

EPS in Australian dollars  
On 2/27/12, exchange rate was  
USD\$1.00:AUD\$0.94

**BI-ANNUAL EPS:**

	Current	Prior
2013E		
Dec	\$0.01	
Jun	\$0.06	
2012E		
Dec A	(\$0.24)	(\$0.22)
Jun	(\$0.04)	(\$0.01)

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**HIGHLIGHTS**

On 2/27/12, GENE reported fiscal 1H12 financial results roughly in line with our forecast and provided an update on the U.S. commercial launch of BREVAGen. Importantly, reimbursement for BREVAGen is tracking ahead of our forecast as GENE has already signed up 4 large preferred provider organizations (PPOs) and is in discussions with several private payers. The company did not disclose revenue per test, but management noted reimbursement for adjudicated claims was above internal forecasts. The company's sales team called on 2,325 physicians including most of its tier 1 accounts, placed 1,320 BREVAGen kits with 246 target accounts resulting in 125 tests ordered (slightly below our estimate of 309 tests). On 2/16/12, GENE received certificate of compliance for its lab under CLIA. Certification allows BREVAGen to be sold in California, Florida, Maryland, Nevada, Pennsylvania, Rhode Island and Tennessee. The test can now be sold in 49 states and GENE plans to apply for clearance in New York this year. 1H12 EPS of (\$0.24) per ADR was (\$0.24), \$0.02 below our estimate of (\$0.22) based on higher-than-expected COGS associated with relatively low test volumes of BREVAGen. We remain upbeat about the near term prospects for new license agreements as several of the patent assertion cases have entered discovery. We reiterate our forecast of \$6M of revenue from patent settlements in 2H12.

- **1H12 Financial Review – Results In Line with Forecast:** GENE reported 1H12 financial results generally in line with our forecast on most metrics, with exception of the Australian testing revenue and gross margins. Genetic testing revenues of \$1.9M were \$0.5M below our forecast as the previously reported slowdown in certain government ordering was more significant than we had forecast. The lower Australian testing volumes and the cost of running relatively small lots of BREVAGen during the initial launch resulted in gross margin of 56.4% (450 basis points below our forecast).
- **Trimming BREVAGen Test Volumes; Reimbursement Ahead of Forecast:** We are trimming our full year test volume estimate from 1,932 tests to 1,166 tests as we believe GENE is focusing on securing appropriate reimbursement before pushing for higher test volumes. On net, the BREVAGen launch is progressing in line with our expectations. As with all molecular diagnostic product launches, test volume growth accelerates with broader reimbursement coverage. The key metrics for initial launch are medical education and physician awareness, in our view. We believe 1H12 test placements of 1,320 kits bodes well for future adoption and completion of a second validation study in calendar 2012 should drive additional physician awareness and comfort with BREVAGen.
- **Australian BRCA Patent Trial a Non-Event:** We believe recent weakness in GENE shares may be related to an ongoing trial in Australia seeking to invalidate the BRCA1 and BRCA2 patents (GENE is the Australian licensee of the patents). We'd note these patents have not been enforced in recent years and several firms already offer testing. As such, we view the trial as a non-event.

All \$ in Australian Dollars unless noted; U.S. Dollar notation (US\$)

Disclosures and Analyst Certifications can be found in Appendix A.

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Table 1.

Genetic Technologies Income Statement										
(in \$ millions except per share)	2011A	1H12A	2H12E	2012E	1H13E	2H13E	2013E	1H14E	2H14E	2014E
BrevaGen sales	\$0.0	\$0.0	\$0.2	\$0.2	\$1.2	\$2.0	\$3.1	\$3.3	\$5.2	\$8.5
Genetic Testing Services	4.6	1.9	2.2	4.1	2.3	2.2	4.5	2.3	2.2	4.5
License Fees and Other Revenue	13.7	1.7	6.0	7.7	6.4	7.0	13.4	8.6	9.2	17.8
Total Revenue	\$18.3	\$3.7	\$8.4	\$12.1	\$9.8	\$11.2	\$21.0	\$14.2	\$16.6	\$30.8
COGS	6.1	1.6	2.9	4.5	3.3	3.7	7.0	4.6	5.3	9.9
Gross profit	\$12.1	\$2.1	\$5.6	\$7.6	\$6.5	\$7.5	\$14.0	\$9.6	\$11.3	\$20.9
G&A	3.8	1.9	1.9	3.8	1.8	1.8	3.6	1.7	1.7	3.4
Research & development	4.4	2.0	2.0	4.0	2.0	2.0	4.0	2.0	2.0	4.0
Sales and Marketing	3.0	2.0	2.2	4.2	2.6	2.9	5.5	3.3	3.2	6.5
Operating profit (loss)	\$1.0	(\$3.8)	(\$0.6)	(\$4.3)	\$0.1	\$0.8	\$0.9	\$2.6	\$4.3	\$6.9
Interest income (expense)	0.2	0.5	0.0	0.5	0.0	0.0	0.0	0.1	0.1	0.1
Taxes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.8	1.3	2.1
Net profit (loss)	1.2	(3.3)	(0.5)	(3.9)	0.2	0.8	1.0	1.8	3.1	4.9
Earnings (loss) per share	\$0.09	(\$0.24)	(\$0.04)	(\$0.28)	\$0.01	\$0.06	\$0.07	\$0.13	\$0.22	\$0.36
Profit (loss) from Discontinued Operations	\$0.00	(\$0.00)	\$0.00	(\$0.00)	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Net income (loss) as reported	0.9	(3.3)	(0.5)	(3.9)	0.2	0.8	1.0	1.8	3.1	4.9
Profit (loss) per share as reported	\$0.07	(\$0.24)	(\$0.04)	(\$0.28)	\$0.01	\$0.06	\$0.07	\$0.13	\$0.22	\$0.36
Weighted average common shares (ADR)	13.5	13.8	13.8	13.8	13.8	13.8	13.8	13.8	13.8	13.8
<b>Margin Analysis</b>										
Gross Margin	66.4%	56.4%	66.0%	63.1%	66.5%	67.0%	66.8%	67.6%	68.0%	67.8%
Operating Margin	5.3%	-103.2%	-6.7%	-35.8%	1.4%	6.8%	4.3%	18.2%	26.1%	22.4%
Net Margin	0.5%	-6.6%	-0.5%	-2.3%	0.1%	0.5%	0.3%	0.9%	1.3%	1.2%

Source: Company reports and Ladenburg Thalmann estimates

Table 2.

Expected Near-term Events		
Event	Time (Fiscal Year)	Importance
In-licensing of 2nd oncology diagnostic test for U.S. market	2H12	High
Filing of 4th round of patent assertion claims	2H12	Medium
Validation data from expanded BREVAGen SNP panel	2H12	High
Validation of BREVAGen in Hispanic population	2H12	High
Publication of BREVAGen pharmacoeconomic study	1H13	Low
Launch of 2nd diagnostic in the U.S.	1H13	Medium
Filing of 5th round of patent assertion claims	1H13	Medium
In-licensing of 3rd oncology diagnostic test for U.S. market	2H13	High

Source: Ladenburg Thalmann estimates

## APPENDIX A: IMPORTANT RESEARCH DISCLOSURES

### ANALYST CERTIFICATION

I, Kevin DeGeeter, attest that the views expressed in this research report accurately reflect my personal views about the subject security and issuer. Furthermore, no part of my compensation was, is, or will be directly or indirectly related to the specific recommendation or views expressed in this research report.

The research analyst(s) primarily responsible for the preparation of this research report have received compensation based upon various factors, including the firm's total revenues, a portion of which is generated by investment banking activities.

### COMPANY BACKGROUND

Genetic Technologies is a genetic testing laboratory based in Melbourne, Australia with operations in Australia, Southeast Asia and the U.S. In June 2011, GENE launched BREVAGen in the U.S. for assessing a woman's risk of developing breast cancer based on clinical characteristics and analysis of a panel of somatic mutations. The Australian operations provide genetic testing for cancer risk assessment, paternity and forensics. The company also derives significant revenue from licensing of patents and other intellectual property pertaining to the role of non-coding DNA and related applications for diagnostic testing.

### VALUATION METHODOLOGY

We currently rate GENE shares at BUY with a price target of \$7.50 based on 25x multiple on 2014 earnings per ADR of \$0.36 discounted back at a 20% cost of capital.

### RISKS

We think the primary risks of an investment in GENE shares include, but are not limited to: Competition: While BREVAGen faces limited direct competition, adoption of the product may be impacted by general acceptance of Gail score compared to other clinical measures for breast cancer risk and by the general availability and cost of SNP testing. In certain academic oncology settings BREVAGen may compete with internally developed risk assessment tools. Additionally, the Australian operations face competition from private and public laboratories. There can be no assurance the performance differences between BREVAGen and other tests will offer a sustainable competitive advantage. Regulatory: GENE is subject to clinical laboratory regulations by regulators in both Australia and the United States under the auspicious of the National Association of Testing Authority (NATA), and CLIA, respectively. Additionally, the company may eventually seek FDA 510(k) or PMA clearance for BREVAGen. There can be no assurance validation studies and subsequent registration studies will be adequate to support PMA or 510(k) clearance of BREVAGen as a screening test for somatic genetic risk of breast cancer. Additionally, there can be no assurance the intended use claim for an expanded SNP panel for BREVAGen will offer clinically important differentiation from the 7-SNP first generation BREVAGen test. Reimbursement: There are no specific treatment guidelines recommending tests such as BREVAGen that combine clinical risk assessment and genetic analysis, and limited payer experience interpreting the clinical utility of combining clinical and genetic measures of risk into a single test for risk assessment. We expect initial reimbursement to be based primarily on CPT code stacking for the set number of SNPs in BREVAGen. While early experience suggests payers will reimburse for BREVAGen based on code stacking, there can be no assurance of broad coverage based on this methodology or that future changes to the application of code stacking will not adversely impact BREVAGen reimbursement rates. Currency: The functional and reporting currency for GENE is the Australian dollar. However, an increasing portion of the company's operating expenses and a small but growing portion of revenues are denominated in U.S. dollars. Additionally, the company maintains active and liquid public stock listings on both the Australian Stock Exchange and NASDAQ. While the exchange rate of the Australian dollar to U.S. dollar has historically been relatively stable, there can be no assurance future volatility in currency exchange rates will not materially impact the cost of funding the company's U.S. operations or impact the price movement of common shares trading on the Australian Stock Exchange or ADRs trading on NASDAQ. SEC reporting requirements may differ slightly from U.S. based entities and investors may not be afforded the same protection or information as a U.S. based entity. Additionally, trading volume has been historically low which could impact an investor's investment. Supply Chain: GENE ships BREVAGen samples from the United States to its laboratory in Australia for analysis and expects to maintain a similar supply chain for any new tests launched in the United States, at least over the near term. There can be no assurance disruptions to international air travel or changes to trade regulations between Australia and the United States will not adversely impact the company's relationships with clinicians or GENE's strategy for expanding its molecular diagnostic business in the United States. Financing: The company believes its financial resources will fund operations through at least 2012. However, depending on the pace of BREVAGen adoption and capital requirements to expand the oncology products portfolio through internal development or acquisition, GENE may need additional capital to fund U.S. expansion. There can be no assurance GENE will have access to private capital in the future on adequate terms, or at all. Intellectual Property: GENE relies on license agreements related to issued patents for a majority of its revenue. Additionally, the company has several pending method patent applications pertaining to BREVAGen. There can be no assurance changes to U.S. patent law or interpretation will not adversely impact the company's future revenues.

### STOCK RATING DEFINITIONS

Buy: The stock's return is expected to exceed 12.5% over the next twelve months.

Neutral: The stock's return is expected to be plus or minus 12.5% over the next twelve months.

Sell: The stock's return is expected to be negative 12.5% or more over the next twelve months.

Investment Ratings are determined by the ranges described above at the time of initiation of coverage, a change in risk, or a change in target price. At other times, the expected returns may fall outside of these ranges because of price movement and/or volatility. Such interim deviations from specified ranges will be permitted but will become subject to review.

#### **RATINGS DISPERSION AND BANKING RELATIONSHIPS (AS OF 1/31/12)**

Buy:	76%	(31% are banking clients)
Neutral:	24%	(10% are banking clients)
Sell:	0%	( 0% are banking clients)

#### **PERSONALIZED MEDICINE STOCKS UNDER AUTHOR ANALYST COVERAGE (“The Universe”)**

BG Medicine (BGMD), Exact Sciences (EXAS), Genetic Technologies (GENE), Genomic Health (GHDX), Myriad Genetics (MYGN), Navidea Biopharmaceuticals (NAVB), NeoGenomics (NGNM), OPKO Health (OPK), Response Genetics (RGDX), Sequenom (SQNM), SeraCare Life Sciences (SRLS) and Vermillion (VRML).

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