



BUY

12 Month Target

25 cents

Price

9.4 cents

Implied Return

166%

Genetic Technologies (GTG)

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2 July 2013

Hitting all the milestones

Company Details

ASX Code:	GTG
NASDAQ ADR Code	GENE
Price:	9.4 cents
Shares on Issue:	475m
Market Capitalisation:	\$44m
12-Month Price Range:	6.0 - 15.0 cents
Monthly Volume (shares, June 13)	2.4 million

Financials

Year ending Jun	2012	2013F	2014F	2015F
Lodge adj profit	(5,297)	(7,668)	(4,644)	372
Reported profit (pre abn)	(5,297)	(7,668)	(4,644)	372
EPS pre goodwill (¢)	(1.1)	(1.6)	(1.0)	0.1
EPS growth	-83.5%	-44.8%	39.4%	108.0%
P/E ratio	-8.3 x	-5.7 x	-9.4 x	117.7 x
DPS (¢)	0.0	0.0	0.0	0.0
Yield	0.0%	0.0%	0.0%	0.0%
Franking	0%	0%	0%	0%
Payout ratio	0%	0%	0%	0%
EV / EBIT	-5.9 x	-5.3 x	-9.5 x	261.6 x
EV / EBITDA	-6.7 x	-6.0 x	-10.1 x	116.5 x
FCFPS (¢)	(1.7)	(1.5)	(0.9)	0.2
Price / FCFPS	-5.7 x	-6.2 x	-10.9 x	45.0 x
NTA per share	\$0.03	\$0.01	\$0.002	\$0.003
Pr / NTA	3.4 x	8.1 x	47.6 x	31.1 x

Directors & Chief Executive

Dr Malcolm Brandon	Non-Executive Chairman
Mr Tommaso Bonvino	Non-Executive Director
Dr Mervyn Cass	Non-Executive Director
Mr Ben Silluzio	Non-Executive Director
Ms Alison Mew	Chief Executive Officer

Major Shareholders

Dr Mervyn Jacobson	28.7%
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Share Price Chart



Source: FactSet

Genetic Technologies Limited is an Australian Securities Exchange (GTG) and NASDAQ (GENE) listed molecular diagnostics company, focussed on the rollout of its breast cancer risk test, BREVAGen™. The Company also retains a substantial intellectual property Portfolio from which it receives a stream of non-dilutive revenues.

Company overview: Genetic Technologies has progressively been reinventing itself over the last few years from what was largely a specialist pathology company with range of other activities to a company that is now firmly focussed on the commercialisation of its breast cancer risk test, BREVAGen™, in the United States.

BREVAGen™ examines a woman's DNA for what are termed single nucleotide polymorphisms that have been shown to be linked to increased risk of developing breast cancer and combines this information with clinical risk factors to improve the estimation of a patient's risk of developing breast cancer. **This information is clinically useful in determining the preventative measures a woman should take to avoid the disease or catch it early.** Unlike Myriad Genetics' BRACAnalysis® test, which looks at two specific, rare, extremely high-risk genes, BREVAGen™ is focussed on defining breast cancer risk for the vast majority of the females, who have either been shown not to carry these high-risk genes or do not have a family or personal history that suggests they might carry either of those genes (i.e. **nearly all females**).

Commercialisation of a test such as BREVAGen™ is a complex process involving the recruitment of key opinion leaders to champion the product, identifying and penetrating key groups likely to be early adopters of the technology, developing and implementing a strategy to get paid for performing the test and continuing to produce scientific publications which support and expand the market for the product.

To this end, the company has been making great strides in recent times. **1H FY13 unit sales were up 240%, Q3 FY13 were up 256% and Q4 FY13 were up 272% compared to the PCP.** The company has also significantly increased the number of lives covered for the test from 13 million at the start of CY13 to the present 102 million. This is important for three reasons. 1) The level of payment received by the company is higher when the test is performed on a patient with coverage, 2) the time to payment is quicker and 3) importantly, it acts as a positive signal to the healthcare community regarding the utility of BREVAGen™.

Based on the information at hand, it is now clear the commercial premise on which BREVAGen™ is based is sound.

Recently, a second paper was published validating BREVAGen™, demonstrating, again, that it significantly improves the discriminatory value of breast cancer risk assessment relative to a standard method (Breast Cancer Res Treat. 2013 Jun 18). The company is also likely to expand the population to which BREVAGen™ is applicable by conducting validation studies in Hispanic and Black populations. Further cost-effectiveness studies will supplement an existing study (J Clin Oncol 28:15s, 2010 (suppl; abstr 6042)), indicating the use of BREVAGen™ saves healthcare dollars, which is important from a payer perspective. All of which will increase BREVAGen™'s commercial prospects.

Recently, a ruling by the US Supreme Court invalidated key claims in certain patents held by Myriad covering the high risk genes mentioned above. Genetic Technologies, as a licensee of the Myriad patents, has been performing testing for those high risk genes for over ten years now and they are one of the very few companies in a position to offer such testing to the US women in competition to Myriad in the near term. We believe the combination of those tests with BREVAGen™ is a highly compelling product offering and find it conceivable that Myriad could seek to acquire BREVAGen™ or Genetic Technologies to protect and grow their existing franchise.

Licensing: Other rulings by the Supreme Court have adversely affected Genetic Technologies' ability to derive licensing revenues from its patent estate. The company has changed its licensing strategy, accordingly, and licensing revenues have begun to flow again, with \$2.5 million received in 1H FY13 and four licences granted so far in the current HF. **We have forecast modest, but significant, revenues going forward of \$4 million per year.** It is likely, these revenues will surprise on the upside.

Other Assets, Restructuring: Genetic Technologies has various assets from which it could realise value over the coming years, including a \$4.45 million equity stake in an oncology company. Additionally, we believe the company can make further cost efficiency changes at its Australian laboratory.

Recommendation: The commercialisation of BREVAGen™ is progressing very well and licensing revenues are steadily flowing, again, consequently, we recommend the company as a **BUY** with a 12-month price target of **25 cents**.

Introduction

Over the last nine months, Genetic Technologies has been regularly hitting its milestones commercially.

The future of Genetic Technologies is its breast cancer risk test, BREVAGen™

It is clear that the company is firmly focussed on the commercialisation of its breast cancer risk test, BREVAGen™, in the United States and it is equally clear **that BREVAGen™ represents the company's future**. In addition, revenues from the company's longstanding program to realise value from seminal patents it owns in the area of genetic analysis have begun to flow again after a lean FY12.

Market acceptance of BREVAGen™ has been demonstrated

BREVAGen™ is a "laboratory developed test", or LDT, that refines a woman's risk of developing breast cancer. Prior to BREVAGen™, clinicians' used the answer to a series of clinical questions, such as age at first live birth, to estimate a woman's risk of developing breast cancer. Essentially, BREVAGen™ enables this risk assessment to include "hard" genetic information. The test has now been on the market in the US for a little less than two years. Strong growth in unit sales, particularly over the last year, and the signing of several agreements with preferred provider organisations (PPOs), as an intermediate step to negotiations directly with insurers for payment, demonstrate **the market has and will continue to accept BREVAGen™**.

Very recently, a decision by the US Supreme Court (SCOTUS) (Association for Molecular Pathology et al. v. Myriad Genetics, inc., et al.), appears to have opened up the market for testing for two genes (BRCA1 & BRCA2) that are associated with dramatically increased risk of breast and ovarian cancer among women who carry a mutated form of one of the genes. Based on its monopoly over these genes, Myriad Genetics (NASDAQ: MYGN) grew to be valued at approximately US\$2.5b, recording US\$496m in revenues for FY12.

A recent decision by the US Supreme Court has created a real opportunity for Genetic Technologies to enter an additional segment of the breast cancer risk testing market

There is a reasonable amount of know-how involved in testing for mutant forms of BRCA1 and BRCA2, know-how Genetic Technologies has, given it has been conducting such testing for over 10 years under licence from Myriad. Consequently, Genetic Technologies appears to be one of the few companies in a position to offer BRCA testing to American women, as a result of Myriad's weakened intellectual property position. As discussed below, **combined with BREVAGen™, this would give Genetic Technologies quite a compelling product offering, which could lead Myriad to bid for the company or BREVAGen™, in our view**.

Genetic Technologies also owns several seminal patents related to the use of non-coding or "junk" DNA in genetic (pertaining to a gene) and genomic (pertaining to the chromosomes) analysis. These patents have been widely infringed and the company has generated significant revenues by asserting its rights to these patents.

Genetic Technologies intellectual property licencing program is generating significant cash flow, again

Shortly after we initiated coverage two decisions were handed down by SCOTUS which adversely affected the company's ability to assert these rights. While the decisions affected the company's assertion program, they also caused targets of the company's suits that were *not affected* by the decisions to more strongly resist settlement, simply based on the new atmosphere the decisions created. As time has passed, however, the company has successfully altered its assertion strategy and the initial resistance these decisions created amongst targets has waned to some extent. **Consequently, the funds have begun to flow from the program, again**.

Valuation Methodology and Valuation

We have used a discounted cash flow methodology to arrive at a 12-month price target of 25 cents per share for Genetic Technologies. This model is based on the following assumptions:

- a discount rate of 15%,
- an exchange rate of 1 AUD=USD0.90,
- a BREVAGen™ cost of goods sold of 15%,
- average payment per BREVAGen™ test of US\$850,
- BREVAGen™ price increases of 15% every two years (similar to those achieved by Myriad with BRCA1 & 2 testing),
- selling, general and administrative expenses associated with the US operations of 100% of sales revenue in FY14, 50% in FY15 and 40% in the years after,

- 200% growth in BREVAGen™ sales in FY14; 160% in FY15; 120% in FY16; 80% in FY17; 40% in FY18; 10% in FY19 and 7% thereafter,
- a terminal growth rate of 1.5%, and
- licensing revenues of \$4 million per year over the duration of the model.

BREVAGen™

BREVAGen™ provides an estimate of a woman's breast cancer risk with greater discriminatory value

BREVAGen™ works by examining a woman's DNA for the presence of seven different single nucleotide polymorphisms, referred to as SNPs (pronounced "snips"). The information from these SNPs is then combined with the information collected from a well-established clinical algorithm, to provide an estimate of a woman's 5-year and lifetime risk of developing breast cancer. The estimates provided by BREVAGen™ provide better discriminatory value than those based on the clinical algorithm alone (J Natl Cancer Inst. 2010 Nov 3;102(21):1618-27; Breast Cancer Res Treat. 2013 Jun 18).

DNA is composed very long chains of nucleotides, with a total of four different nucleotides represented (adenine, cytosine, guanine and thymine). As has been shown in several peer-reviewed research publications, the presence of a particular nucleotide at a particular position in the DNA can be linked to particular diseases or susceptibility to particular diseases. In the case of BREVAGen™, each of the SNPs BREVAGen™ looks at is associated with a higher than average risk of the occurrence of breast cancer.

BREVAGen™ provides information upon which a doctor can act; a key requirement of a successful test

For a test to be valuable, it needs to provide the physician with actionable information. That is, it needs to provide the doctor with information that allows them to better care for their patient. In the case of BREVAGen™, the information it provides can be used to justify the prophylactic (preventative) use of a drug called tamoxifen and/or the use of a more expensive, but more sensitive, breast cancer screening tool, termed magnetic resonance imaging. On the flip-side, but less likely, it may provide information that leads to a patient being screened less intensively. **Consequently, BREVAGen™ provides actionable information to physicians.**

Importantly, initial modelling has shown BREVAGen™ to be cost-effective (J Clin Oncol 28:15s, 2010 (suppl; abstr 6042)). That is, healthcare payers (be it the patient, insurance company and/or government in the US), will save money through the use of BREVAGen™. This is occurs for several reasons, including:

BREVAGen™ is also likely to save healthcare dollars via a variety of mechanisms

- the high cost of treating late stage breast cancer patients,
- prevention of breast cancer through the use of tamoxifen,
- earlier detection of breast cancer through the use of MRI at a stage where it is easier and less expensive to treat,
- and the elimination of expenses associated intensively screening women who would be better served by less-intensive screening regimens, based on their true breast cancer risk.

BREVAGen™ Sales

Strong recent BREVAGen™ sales growth

BREVAGen™ sales have been steadily improving, with a 1H FY13 total of 546 tests. This represents a 240% increase over the PCP. The number of tests received in Q3 FY13 was 403, while the number received in Q4 FY13 was 599, representing growth of 256% and 272%, respectively, on a PCP basis.

Based on the data available, BREVAGen™ sales have been growing at an average rate of 28% on a quarter-on-quarter basis, excluding the most recent quarter (Q4 FY13). **We believe this sort of growth rate, perhaps higher in the near-term, is sustainable for, at least, two years going forward.** We believe so, because:

We believe this sales growth is sustainable for a number reasons

- the commercial utility of the test has now been demonstrated,
- the number of PPOs offering the test continues to increase (coverage by PPOs sends a positive signal to the market regarding the utility of BREVAGen™),
- the company still has relatively few sales representatives (approximately 10-12) on the ground in the US and can easily increase its sales force when it is justified,
- initial marketing efforts have been greatly improved under the new US-based Vice

President, Sales and Marketing,

- a further study validating BREVAGen™ has been recently published (Breast Cancer Res Treat. 2013 Jun 18), which will convince more physicians to prescribe BREVAGen™,
- further peer-reviewed scientific publications supporting BREVAGen™ are likely to be produced which will enable greater penetration into existing markets, expand the overall market for BREVAGen™, while also aiding the company in negotiations with payers, and
- scope exists to sell other tests, such as analysis of the BRCA1 and BRCA2 genes, through the US-based sales team Genetic Technologies has created.

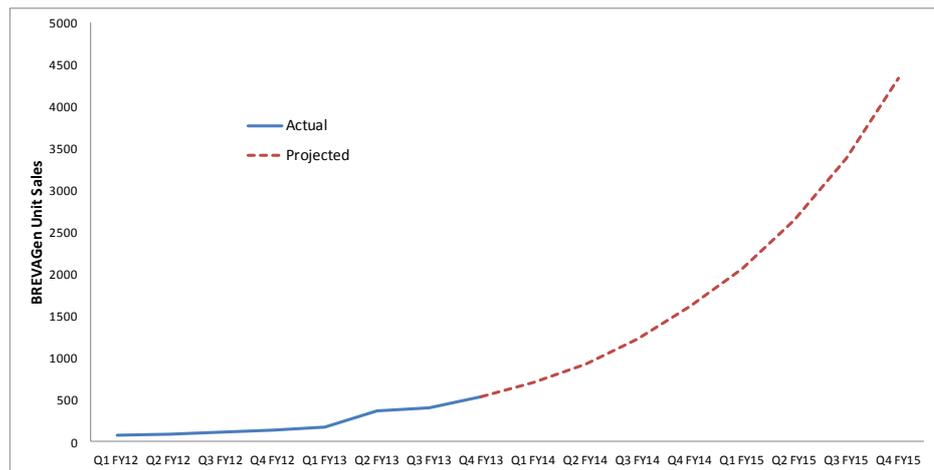
The new US-based Vice President, Sales and Marketing is capable of accelerating growth beyond historical rates in our opinion

Figure 1 provides a graphical representation of BREVAGen™'s actual unit sales to date and our projected sales going forward. We have assumed 32% quarter-on-quarter growth for FY14 and 28% for FY15, which represent 202% and 160% yearly growth rates, respectively. As stated above, BREVAGen™ sales have grown at an average rate of 28% quarter-on-quarter historically. We have ascribed a higher growth rate for FY14 than that seen historically largely based on our belief that the US-based Vice President of Sales and Marketing appointed last September will be capable of growing sales more quickly than his predecessor.

Strong growth likely this quarter

While the graph gives the impression of relatively consistent growth, the reality is that growth is likely to vary from quarter to quarter. In fact, historically, quarter-on-quarter growth rates have varied between 10% and 52%. While this variation will decrease as sales grow, it is still likely that significant variation will occur in the nearer term. Moreover, we expect some seasonality in sales to be revealed (e.g. The 2nd quarter of the FY is, generally, Sirtex Medical Limited's (SRX; Sell) weakest quarter of sales of its cancer therapy). Presently, a low prescribing period by one of the company's higher prescribers for any of a variety of reasons is quite capable of depressing BREVAGen™'s sales growth rate. Having said that, the converse is also true, adoption by high a few high prescribers in any quarter is capable of accelerating growth considerably. **For example, Q4 FY13 sales have come in at 499 units, displaying quarter-on-quarter growth of 49%**

Figure 1. Actual and Project Quarterly BREVAGen™ Unit Sales. Source: Genetic Technologies' company announcements and Lodge estimates.



Genetic Technologies is still accounting for BREVAGen™ revenues on a cash basis and, given it is normal for payment times to be well in excess of 90 days for newly launched LDT's, it is hard to get a completely accurate read on the average payment the company is receiving for each BREVAGen™ test. Our analysis indicates that prior to December 2012, payment probably averaged in the US\$500-\$600 dollar range per test. It is more difficult to determine how much the company is receiving per test after that date, given changes to the payment landscape that came into effect on the 1st January 2013.

Prior to the 1st of January, Genetic Technologies had been charging for BREVAGen™ via a ‘stacked’ Current Procedural Terminology or CPT code; a common way in which LDT’s previously gained payment from insurers in the US. Under a stacked CPT code, the payer is charged based on the routine steps involved in an analysis (e.g. one sample extraction, two polymerase chain reaction steps, etc.), with a CPT code defining the payment for each step. It is also important to recognise that under this system, the payer does not know exactly what test they are being charged for, just the steps involved, unless they inquire further.

As of the new year, ‘stacked’ CPT codes were eliminated and replaced with a miscellaneous code, which presented both an opportunity and a risk to companies that sold tests like BREVAGen™.

The opportunity was that under the stacked CPT code system, the intellectual property, such as an algorithm, around a test **could NOT be charged for**, whereas **it can be charged for under the new miscellaneous code**. The risk, however, was that under the miscellaneous code, the company performing the test had to give the insurer a greater amount of detail about what they were being charged for. Essentially, the ability of LDT’s to fly under insurers’ radars was removed, but in so doing the company providing the test now had the opportunity to charge more and provide the insurer with information regarding the utility of the test to justify that charge.

Changes to the payment method appear to have been a positive for the company

While it is still relatively early days in terms of gauging the impact of the change to the coding system on BREVAGen™ payment rates and times, initial reports from the company have been positive. They have indicated the change has had minimal, if any, negative impact on sales and payment times. Moreover, we believe that the company has taken the opportunity to increase its price for the test and that **closed cases (i.e. where the test has been performed and payment received) so far have seen average payments in the US\$800 - \$900 range, significantly more than the company was likely receiving under the “stacked” CPT method.**

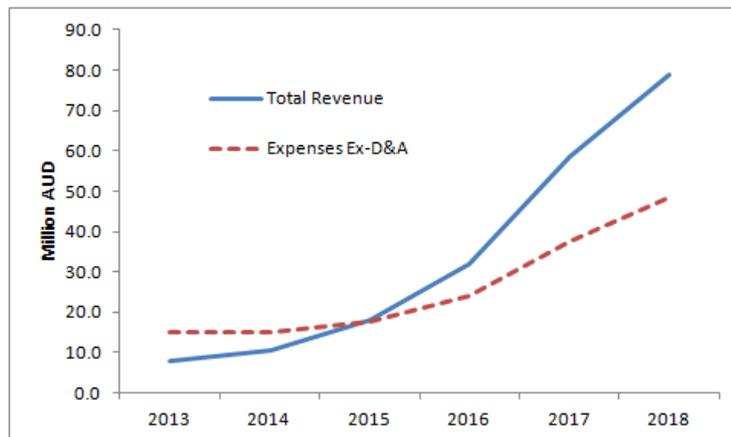
Genetic Technologies is probably now getting close to having enough information to switch from accounting for BREVAGen™ sales on a cash basis to an accrual basis, with an adjustment made at the end of each period to account for the amount of cash recorded and the amount of cash actually received. This change will give investors a fair bit more clarity than they have previously had regarding BREVAGen™ revenues.

Breakeven Point

We forecast breakeven in FY15

We are forecasting Genetic Technologies to turn a small profit in FY15, as illustrated in figure 2, with BREVAGen™ sales becoming cash flow positive during that year. The company should be profitable based on BREVAGen™ sales alone (i.e. without any contribution from patent assertion) in FY16. The company becomes breakeven on BREVAGen™ revenues alone at approximately 1000 tests per month and over this number much of the revenue generated hits the bottom line. It is currently selling about 200 tests a month.

Figure 2. Projected revenues and expenses for Genetic Technologies for the next six years. Source: Lodge estimates.



These projected figures assume Genetic Technologies can:

- grow the sales of BREVAGen™, as described earlier,
- collect payment of \$850 per test on average,
- add sales representatives for BREVAGen™ as and when needed,
- maintain tight control on selling, general and administrative expenses in the US,
- reduce its Australian cost base over the coming year and, to a lesser extent, the year after,
- continue to increase the number of lives covered applicable to BREVAGen™ and
- generate \$4m in licensing revenues a year from its patent estate.

The figures do not:

- assume additional products, such as BRCA testing, are sold through Genetic Technologies sales representatives in the US,
- require BREVAGen™ to be validated for and sold into ethnic groups other than Caucasians,
- require penetration rates of initial target markets, describe later, of greater 0.5% in 2015 and 2.5% in 2018,
- include any sales of non-core assets, such as the company's stake in ImmunAid, which has a value of \$4.45 million based on the price of ImmunAid's last capital raise, and
- sales in other jurisdictions. BREVAGen™ is CE Marked, meaning it can be sold in the European Union. A distributor simply needs to be appointed.

While unit sales will always be a key metric going forward, we believe that market acceptance of BREVAGen™ has been demonstrated. **The next question is how quickly can they grow sales and at what cost.** The inclusion of the heritage genetic testing business in the company's financial statements reduces transparency in this area somewhat. Nonetheless, investors should be able to gain a reasonable read on this metric by assuming that the heritage business (similar to a standard pathology laboratory) is cash neutral in terms of operations, initially, and that it can be rationalised to some extent going forward.

How costs scale with BREVAGen™ sales going forward is a key metric

The Potential to Add BRCA Testing to the Company's Product Offering

As stated previously, Genetic Technologies is one of the few companies in a position to quickly offer testing for two key high risk breast cancer genes, BRCA1 and BRCA2, now that key claims in patents held by Myriad Genetics have been invalidated. And it makes great sense for the company to do so for a variety of reasons, most of all because those patients who test negative for the BRCA genes will have a heightened awareness of breast cancer risk and likely be keen to know as much as they can about their breast cancer risk. This makes the combination offering of BRCA testing and BREVAGen™ quite a compelling commercial prospect.

BREVAGen™ plus BRCA testing would be quite a compelling product offering

While the demonstrated path to success for molecular diagnostics, like BREVAGen™, is for the company who owns the product to build a sales force and sell the product themselves, building and maintaining this sales force, particularly in the early stages of commercialisation, is expensive. Therefore, the more products a company can push through this sales force, the better and adding BRCA testing to BREVAGen™ would place very few extra demands on Genetic Technologies existing BREVAGen™ sales force.

Little extra cost involved in offering BRCA testing

Myriad currently charges approximately US\$3,000 for its BRCA test, BRACAnalysis®. Analysts, however, expect this price to drop to approximately US\$1,000 when competitors begin to offer the test. Myriad currently operates on gross margin of approximately 85%. Consequently, even at a price of US\$1,000, the gross margin on BRCA testing would be approximately US\$550 per test. If Genetic Technologies were to offer BRCA testing, expenses (ex-cost of goods sold) would be unlikely to increase much and, consequently, most of this gross margin would fall straight to the bottom line.

Could bring significant revenues straight to the bottom line

Myriad's strategy post-BRCA patent protection is not overly strong in our opinion

Myriad's strategy to deal with the impending expiry of its patents on BRCA genes was to offer a panel of tests for inherited cancers. It appears that this is still the strategy, now that Myriad's intellectual property position is significantly weaker than it once was. To us, this strategy makes little sense. A patient is unlucky enough to inherit one cancer gene, much less two. That is, the value add by testing for an inherited cancer a patient is extremely unlikely to have seems highly limited. Moreover, many inherited forms of cancer come as part of a syndrome that a doctor can diagnose without a genetic test (e.g. familial adenomatous polyposis), making the value of test limited, given the doctor already has the actionable information he needs from the clinical assessment of the patient.

Myriad could look to acquire Genetic Technologies or BREVAGen™ to protect its franchise

As a consequence, we believe that Myriad will seriously consider buying either BREVAGen™ or Genetic Technologies. It is known that the two companies' are in contact with each other, given Genetic Technologies is a licensee of some of Myriad's patents and vice versa. While it is difficult to gauge what a deal would look like at this stage, the fact that Genetic Technologies has demonstrated commercial acceptance of BREVAGen™, the price would likely be significant.

Marketing of BREVAGen™ appears to have greatly improved under new, ex-Myriad, executive

The Market for BREVAGen™

The quality of the marketing of BREVAGen™ appears to have improved greatly under Senior Vice-President, Marketing and Sales and ex-Myriad executive, Mark Ostrowski, who replaced his predecessor in September of last year (2012).

The potential market for BREVAGen™ is large; potentially, every woman in the US. The path to that market, however, needs to be traversed carefully, as a mass marketing style campaign almost certainly wouldn't work and would be cost prohibitive. Consequently, Genetic Technologies and Mr Ostrowski have chosen to focus on a few groups where need/benefit from BREVAGen™ is likely to be greatest, with the ultimate aim of penetrating the broader market.

Key markets, largely ordered by benefit/need, for BREVAGen™ are:

1. BRCA1 & BRCA2 negative women,
2. women at intermediate breast cancer risk based on clinical risk factors,
3. women with a weak, but noticeable, family history of breast cancer,
4. women aged over 35 with an interest in their breast health and/or risk factors other than a family history,
5. the broader female population over the age of 35.

Table 1 provides a snapshot of the number of US women within various target markets.

Table 1. US Market Size Estimates for BREVAGen™ . Source: Lodge estimates and US Census Bureau, 2011.

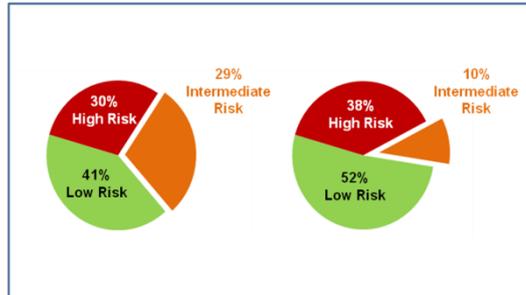
Market	Number of Women
BRCA negative	50,000 – 100,000
Intermediate risk	Approx. 2.8 million
Caucasian, aged 35-59	35 million
Hispanic, aged 35-59	7 million
Black, aged 35-59	7 million
All women, Aged 35-59	52.5 million

Myriad states that it performs approximately 250 thousand BRCA[®] tests each year. While it is not entirely clear, it seems likely that approximately 80% of these tests return a negative result. In cases where a BRCA mutation has been identified in a relative, it is likely that patients who test negative are at average risk of developing breast cancer, although they will have a heightened awareness of breast cancer risk. In the remainder of patients, a number that is hard to quantify, a significant likelihood remains that there is a genetic component involved in the family history of breast cancer that has lead them to have BRCA[®] in the first place. This group of BRCA negative women will be highly conscious of their breast cancer risk and, consequently, represent a relatively easy market to penetrate, with such patients' keen to get the information BREVAGen™ provides. Moreover, physicians who prescribe a high number of BRCA[®] tests are likely to grasp the

BRCA-test negative women is a promising market comprising 50,000-100,000 women a year in the US

benefit of BREVAGEN™, given they already have a strong understanding of breast cancer genetics. **It is not unreasonable to conclude that patients who test BRCA-negative represent a potential BREVAGEN™ market of between 50,000 and 100,000 tests per annum.**

Figure 3. The reclassification of patients' breast cancer risk after BREVAGEN™ testing. Source: Genetic Technologies company presentation.



In terms of clinical performance, the sweet spot for BREVAGEN™ is women who are classified as at intermediate risk of developing breast cancer based on clinical risk factors (commonly referred to as the Gail score, Breast Cancer Risk Assessment Test or BRCAT). BREVAGEN™ has been shown to reclassify 64% of these women into either high or low risk groups, as illustrated in figure 3. A recently published confirmatory study put this figure at 52% (Breast Cancer Res Treat. 2013 Jun 18), although the study included a relatively small number of intermediate risk patients. This re-classification gives physicians' and patients' more certainty regarding the preventative/screening measures they should be taking regarding their risk of developing breast cancer. If a patient is moved up into the high risk group, under most healthcare plans, they will become eligible for screening MRI and prophylactic tamoxifen therapy, as mentioned earlier. If they are moved down to the low risk group, lower frequency screening by mammography is recommended, although the age of commencement and regularity of screening varies depending on the professional guidelines a clinician follows.

Women at an intermediate risk of breast cancer is the 'sweet spot' in terms of BREVAGEN™'s value add

The market comprising women at intermediate risk of breast cancer is a significant market opportunity. Overall, there are about 35 million Caucasian women between the ages of 35 and 59 in the US (US Census Bureau, 2011). Based on the two studies undertaken to validate BREVAGEN™, this market could be anywhere between 1.9 million and 10.2 million. These studies were done in very low risk and very high risk populations, respectively, and, consequently, the true number is somewhere between the two. **We believe a figure of approximately 2.8 million is a reasonable estimate.**

Intermediate risk women represent a market of approximately 2.8 million women in the US

While this is a substantially larger market than the BRCA negative market, penetration rates are unlikely to be as high as for the BRCA-negative market; particularly early on, given BREVAGEN™ is the first real test of its kind for women in this risk category. Nonetheless, as occurred with BRACAnalysis®, physician's eventually grasp the value of new genetic information. Given genetic information plays a much greater role in medicine these days than it did when BRACAnalysis® was first marketed, the rate of penetration is unlikely to be slow.

Initial target markets alone could support our sales forecasts out to 2023

Given our model incorporates test sales of under 100,000 in 2023, these two initial markets alone are probably capable of supporting our growth forecasts.

There will also be a group of women who have a weak family history of breast cancer, but are not candidates for BRCA1 & 2 testing. In general, BRCA testing is only recommended when there is notable early onset of breast and/or ovarian cancer in a patient's family's history and, still, doctors prefer to test an affected family member (i.e. one who has had early onset disease) first, if one is available, before moving on to patients who may have inherited the gene. If BRCA testing is not clinically justified, BREVAGEN™ is clearly a viable option for these women. This market is in the millions of women.

This group of women is likely to overlap with a population of women who take a keen interest in their breast health and will seek to be tested simply to know more about their risk of developing breast cancer. Obviously, women with a weak family history of breast cancer are

more likely to be motivated regarding their breast health. There will also be those who lost a friend/acquaintance to breast cancer, as well as women who are extremely conscious about taking preventative health measures. This market, however, is extremely difficult to quantify.

Ultimate target market is that all US women at some stage in their life be tested by BREVAGen™

Ultimately, the entire female population are candidates for BREVAGen™ testing. The benefit to be gained by a woman of truly average or below average risk (i.e. including clinical risk factors) having a BREVAGen™ test is likely to be subtle. Nonetheless, there will be doctors' and patients' that will see the information BREVAGen™ provides as valuable, even in average/below average breast cancer risk scenarios.

Market penetration rates for BREVAGen™ will likely increase as the number of clinical risk factors a patient presents with increase

When looking at the broader female population, conceptually basing adoption of BREVAGen™ on clinical risk factors intuitively makes sense. That is, for women of below intermediate risk, the more risk factors they have, the more likely it is that they will have a BREVAGen™ test. What penetration and penetration rates for these women might be is, obviously, difficult to determine is only likely to be clear once Genetic Technologies commences actively marketing BREVAGen™ to this group of women.

We see a very logical, well thought out, marketing strategy for BREVAGen™ being implemented

Marketing Strategy for BREVAGen™

As mentioned above, developing the market for BREVAGen™ needs to occur carefully and in a logical fashion. The marketing 'formula' for medical products is generally well defined, although, depending on the particular nature of the product, there will always be some components that are idiosyncratic. Under Mark Ostrowski, we see a logical marketing strategy for BREVAGen™, composed of the following facets, some of which are intertwined:

- recruitment of key opinion leaders,
- targeting of high prescribing BRCA physicians,
- targeting of comprehensive cancer centers,
- maximising payment (credentialing of preferred provider organisation and, subsequent, direct negotiations with insurers),
- expand patient population to which BREVAGen™ is applicable, and
- expand evidence base supporting BREVAGen™.

KOLs are very important and several have been recruited to champion BREVAGen™

When deciding to use a medical product, some physicians look closely at the data supporting the use of that product as published in peer-reviewed scientific journals. Generally, such doctors are early adopters of new technologies and are the ones that other doctors will look to when deciding whether to use a product or not. Consequently, these doctors' tend to be defined as key opinion leaders or KOLs. Genetic Technologies has done a good job using the literature available on BREVAGen™ to recruit KOLs. Once recruited, a KOL can then be used to engage with the broader medical community. Two of the earliest KOLs recruited by Genetic Technologies to support BREVAGen™ were Dr Owen Winslett, of the Breast Center Austin, and Dr Eric Jacoby, of Personalized Women's Healthcare. A Google search for either of these physicians combined the term "BREVAGen" will provide interested parties with examples of the way KOLs are being used to market BREVAGen™.

High prescribing BRACAnalysis® doctors a key target group

As mentioned above, one of the two key initial target markets that Genetic Technologies has gone after is the patients of high prescribing BRACAnalysis® doctors. Again, this makes sense. **Such doctors have a demonstrated willingness to incorporate genetic information in their decision making and, importantly, the ability to quickly grasp the utility of a test like BREVAGen™. Also, they regularly come into contact with women who would benefit from genetic information about their breast cancer risk.** In general, doctors are not experts in genetics, despite genetics playing an ever increasing role in medicine, and initially focusing on physicians who can quickly grasp the utility of BREVAGen™ is likely to speed adoption of the test. Importantly, this strategy also leads to a group of 'specialist' physicians who can explain the utility of the test to their colleagues and further increase sales, much like a KOL.

Comprehensive cancer centers another key target group

In terms of intermediate risk women, the initial marketing focus of BREVAGen™ is on comprehensive cancer centers. Not only do such centers see a large number of patients, but use of a test by such centers can be seen as validation of the test by other physicians and smaller centres. Again, the logic here is similar to that for KOLs and high prescribing BRACAnalysis® doctors; key centers will bring other centers along, driving market adoption of

the test. Bringing on such centers is not an easy task. Their size and decision making processes can be slow. On the other hand, their use of the test is likely to bring benefits far beyond the number of tests the physicians at the centers prescribe, given they will have an influence over other centers and, importantly, payers and their intermediaries. **Insurers, in particular, are influenced by who is using a test and how often it is being used.**

Strategy designed to create a wave driving adoption of BREVAGen™

As should be evident, the net effect of this marketing strategy is to start with early and key adopters to ultimately create a wave big enough to drive adoption of the test through the rest of the market, including coverage of the test directly by insurers.

Another issue that faces companies that make tests like BREVAGen™ is actually getting paid. While US citizens are, generally, used to greater out of pocket expenses with respect to healthcare, they still are used to having another party foot, at least, part of the bill. With a test like BREVAGen™, the bulk of revenues Genetic Technologies receives from performing the test will ultimately come from healthcare insurers.

PPOs are key intermediate step in generating revenues from BREVAGen™, before the company contracts with insurers directly

There is now a well worn path to gaining insurance coverage for tests like BREVAGen™. It starts with a process known as credentialing with PPOs. PPOs are aggregated groups of healthcare providers that contract directly with insurers to provide services, with a set price for each service. Generally, this will be done at a discount (~20%) to standard rates, similar, in a way, to any bulk discount. PPOs ensure patient flows for the healthcare providers, while offering insurance companies the chance to limit costs. The common metric used for agreements with PPOs and insurers is the number of lives covered. In the case of PPOs, this refers to the number of patients that use that organisation. Ultimately, once the clinical usefulness of a product has been adequately demonstrated and the use of the product is widespread enough, a company like Genetic Technologies will then contract directly with insurers.

Genetic Technologies has made very significant progress with PPOs

Currently, the company has signed PPO contracts with 7 PPOs, giving it a total of more than 100 million lives covered. The most recent PPO to sign up was FedMed, Inc. It is also the largest signed up to date, representing approximately 40 million covered lives. As an aside, it is interesting to note that Genetic Technologies share price has tended to rise in the US when it announces a PPO contract, despite the announcement being made to the local bourse first. This probably reflects the US markets greater appreciation of the value of PPO contracts.

PPOs lead to higher and quicker payment for BREVAGen™

We believe more PPO contracts are in the pipeline for Genetic Technologies and this is important. It is generally recognised and Genetic Technologies has noted that BREVAGen™ tests done "in network" (i.e. through a PPO) actually lead to higher payments by insurers, as well as reduced payment times.

The company will need to continue to conduct ongoing research with BREVAGen™ to achieve a number of aims

- support and increase the penetration of BREVAGen™ in the existing Caucasian market,
- further define and quantify the benefit of the test to patients,
- expand the patient population to which BREVAGen™ is applicable (e.g. Hispanics), and
- demonstrate the economic benefits of the use test, particularly to payers, relative to non-use.

A second BREVAGen™ validation study has been published, reaffirming the findings of the first study

To this end, the company has just announced the publication of a second validation study in Breast Cancer Research and Treatment (Breast Cancer Res Treat. 2013 Jun 18). Importantly, the results presented in this paper are similar to the results of the initial validation study of BREVAGen™ published by Mealiffe et al in the Journal of the National Cancer Institute (J Natl Cancer Inst. 2010 Nov 3;102(21):1618-27). That is, the combination of genetic information with clinical information significantly improves the assessment of women's risk of developing breast cancer. Moreover, **the present study re-affirmed that women most likely to benefit from BREVAGen™ testing are those at intermediate risk of breast cancer.** As mentioned earlier, in the present study, 52% of women classified as at

intermediate risk of breast cancer were reclassified upon the inclusion of the genetic information provided by BREVAGen™ compared to 64% in Mealiffe et al. The present study did not have data regarding breast biopsy and was undertaken in a very low risk population, which meant fewer individuals would have been classified as at intermediate risk than expected. The present study was also smaller than the Mealiffe et al study (control arm n=463 and n=1636, respectively). Nonetheless, the concordance of results between the studies is strong and both identify patients at intermediate risk of breast cancer based on clinical risk factors as the key group of patient's likely to benefit from BREVAGen™ testing.

Validating BREVAGen in other races will increase the applicable market size and simplify the marketing of BREVAGen™

Due to the nature of SNPs, it is not scientifically sound to extrapolate the results obtained with one race to other races. Consequently, BREVAGen™ is currently only suitable for and marketed to the approximately 63% of American women who are Caucasians. Obviously, this sort of a restriction limits the overall market which BREVAGen™ is applicable to, but also adds an extra layer of complexity when trying to convince a physician or healthcare facility to use the test. Having said that, validation studies in other races can be done quite quickly provided a suitable bank of samples can be found. Our understanding is that such banks have been identified and it is likely that studies to validate BREVAGen™ in other races will commence shortly. Hispanics are likely to be the first cab off the rank given they represent a significant portion of the US population. Table 1 provides data on the market opportunity some of the non-Caucasian races represent.

In general, continuing to build the scientific evidence to support the use of your product is an ongoing process, rather than a finite one. To this end, we expect the company to support further studies to further define the performance of BREVAGen™ and identify patients who will most benefit from its use. We also expect the company to conduct research looking at the cost effectiveness of the test. Payers are much more likely to pay for a test, if it reduces their overall costs. In the case of BREVAGen™, the relevant costs are those associated with treating cases of breast cancer that might be otherwise prevented or detected at an earlier stage through the use of the test.

Licensing – The ‘179 and ‘762 Patents

Genetic Technologies has generated significant revenues from some seminal patents it owns

Over the years, Genetic Technologies has generated revenue in excess of \$70 million through the issuing of licenses to third parties for non-exclusive use of two patents. These patents, known as the ‘179 and ‘762 patents, are method patents and relate to genetic (gene) analysis and genomic (within the chromosomes) mapping using non-coding DNA. In recent years, the revenues generated via the patents has come as a result of the company suing infringers and, subsequently, settling for a one-off licence fee prior to the case being heard by a court.

US Supreme Court decisions have required Genetic Technologies to alter its strategy for deriving revenue from these patents

As method patents, they are not affected by the recent SCOTUS ruling invalidating gene patents. Two SCOTUS rulings, however, have affected Genetic Technologies' ability to assert its rights. The first was *Global-Tech Appliances, Inc. v. SEB S.A.* and the second was *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* The former ruling related to induced infringement, which occurs when a company sells a product that in its use causes the purchaser to infringe a patent. Without getting bogged down in details, the ruling made it a lot more difficult to demonstrate induced infringement. Given many of the suits Genetic Technologies were focussed on at the time were based around induced infringement; this ruling significantly slowed the company's licencing program. The latter ruling relates to the difference between natural correlations, which are not patentable, and applications of natural correlations, which are patentable. While Genetic Technologies patents appear to be patentable applications of natural correlations (probably better referred to as relationships), the SCOTUS' ruling appears to have made companies less likely to settle with Genetic Technologies, ultimately leading to more drawn out negotiations.

Significant revenues are flowing, again, from these patents

Commencing late August 2012, however, Genetic Technologies, again, began to announce licencing agreements. **For the half year ending December 2012, the company announced licence fees of approximately \$2.5 million, indicating its licencing program is back on track.** It has done so, by altering its strategy to focus on direct infringers and taking advantage of a legislative change that makes it easier/more cost effective for the company to go after smaller infringers.

While the ‘179 patent has expired, Genetic Technologies can still sue for past infringement until approximately 2016, depending on the jurisdiction. The last of the patents in the ‘762

patent family expires in 2015, meaning suits for infringement of this patent can be brought until 2021. Further patents acquired with BREVAGen™ from Perlegen Sciences may also be a source of income, with the earliest of these patents expiring in 2021.

We have forecast modest revenues from the company's licensing program, that are likely to surprise on the upside

Given the rulings of SCOTUS, it has and will likely continue to be harder for Genetic Technologies to derive revenue from its patent estate than it was in the past. Nonetheless, a reasonable, but significant, flow of revenue from these patents is still likely. Consequently, we have included \$4 million per year in licencing revenues going forward into our valuation. We view this figure as relatively conservative.

There may be big deals left to be done

There is the possibility that some large licencing deals may still be done. In March, Genetic Technologies announced that it had begun talks or initiated proceedings in eight different European countries, in addition to its on-going activities in the US. While it is difficult to predict the outcome of these proceedings, it seems likely that, at least, a few of these cases may surprise on the high side in terms of revenue to the company.

The current challenge to the '179 patent is more of an annoyance than anything substantive

Over the years, the company's '179 patent has been repeatedly challenged and the subject of numerous re-examinations. In March 2013, Genetic Technologies announced that the '179 patent had, again, been upheld by the USPTO. The company which had requested this previous re-examination (Meril LLC; a Sanofi company), again, asked the USPTO to re-examine the patent in April 2013 and the USPTO has granted this request. This re-examination is currently on-going. As with previous re-examinations, however, we expect the claims of the '179 patent to be upheld and see the current re-examination as an annoyance rather than anything substantive.

Revenue from Other Assets, Cost Savings

Genetic Technologies has other assets on its balance sheet that it may be able to realise value from.

Genetic Technology has equity in an oncology company worth \$4.45 million on its books

The most significant asset appears to be ImmunAid (public unlisted), an oncology company in which Genetic Technologies has a **\$4.45m stake in, based on the price obtained for shares in ImmunAid's last capital raising**. Further capital raisings by ImmunAid may be at a higher price, which would, obviously, increase its value to Genetic Technologies. It is unlikely, however, that this value will be realised quickly, although it may provide the company with significant cash in the years to come.

Further non-core assets can be sold to generate cash

Genetic Technologies also has a technology for non-invasive amniotic fluid sampling within subsidiary company, RareCollect; an animal testing business that fits poorly with the company's human testing focus; and majority ownership of a Toronto Stock Exchange, secondary venture board, listed shell, Gtech International. These assets may be capable through their sale of generating up to \$2m in cash for the company over the course of the next year or two.

Additional cost efficiencies may be gained at the company's Australian laboratory

In addition, we understand that Genetic Technologies has recently completed a modest restructure, probably related to its animal testing business. We believe this restructure has seen up to five staff members let go. It is not entirely clear what the annual savings of these departures will be, but the company most likely would have incurred a modest one-off restructuring cost that the savings need to be balanced against in the near term. **We think there are probably additional savings that can be made by streamlining the business in the direction of BREVAGen™ and the cessation of further loss-making activities.**

Genetic Technologies Limited (GTG: \$0.094)

Mkt Cap: \$43.8m



Valuation data

Year ending Jun	2012	2013F	2014F	2015F	2016F
Lodge adj profit	(5,297)	(7,668)	(4,644)	372	7,812
Reported profit (pre sig)	(5,297)	(7,668)	(4,644)	372	7,812
EPS_{adj} (¢)	(1.1)	(1.6)	(1.0)	0.1	1.7
EPS _{adj} growth	(622.0%)	(44.8%)	39.4%	108.0%	1997.5%
P/E ratio	-8.3 x	-5.7 x	-9.4 x	117.7 x	5.6 x
DPS (¢)	0.0	0.0	0.0	0.0	0.0
Yield	0.0%	0.0%	0.0%	0.0%	0.0%
Franking	0%	0%	0%	0%	0%
Payout ratio	0%	0%	0%	0%	0%
EV / EBIT	-5.3 x	-9.5 x	261.6 x	4.7 x	0.6 x
EV / EBITDA	-6.0 x	-10.1 x	116.5 x	4.6 x	0.6 x
FCFPS (¢)	(1.7)	(1.5)	(0.9)	0.2	1.9
Price / FCFPS	-5.7 x	-6.2 x	-10.9 x	45.0 x	4.9 x
NTA per share	\$0.03	\$0.01	\$0.002	\$0.003	\$0.02
Pt / NTA	3.4 x	8.1 x	47.6 x	31.1 x	4.7 x

Balance sheet (\$T)

Year ending Jun	2012	2013F	2014F	2015F	2016F
Cash	8,900	1,801	(2,235)	(1,261)	7,753
Receivables	496	781	624	1,052	1,599
Inventories	0	0	0	0	0
Other	554	554	554	554	554
Current assets	9,950	3,136	(1,057)	344	9,906
Net PPE	643	100	100	100	100
Investments	0	0	0	0	0
Intangibles	1,434	1,198	1,016	901	786
FITB	0	0	0	0	0
Other	4,415	4,415	4,415	4,415	4,415
Non-current assets	6,492	5,713	5,531	5,416	5,301
Total assets	16,442	8,849	4,474	5,760	15,207
Debt	924	999	1,267	2,181	3,816
Provisions	849	849	849	849	849
Other	267	267	267	267	267
Total liabilities	2,039	2,114	2,383	3,297	4,932
Equity / reserves	87,000	87,000	87,000	87,000	87,000
Retained profits	(72,752)	(80,419)	(85,063)	(84,691)	(76,879)
Total s/h funds	14,403	6,735	2,091	2,463	10,275
Minorities	0	155	155	155	155
Total funds emp.	6,426	5,932	5,593	5,906	6,338

Ratio analysis

Year ending Jun	2012	2013F	2014F	2015F	2016F
EBITDA / sales	-84%	-85%	-44%	2%	25%
EBITAg / sales	-95%	-96%	-47%	1%	24%
EBIT / sales	-95%	-96%	-47%	1%	24%
Return on assets	-78%	-112%	-72%	2%	102%
Return on equity	-37%	-114%	-222%	15%	76%

Profit and loss (\$T)

Year ending Jun	2012	2013F	2014F	2015F	2016F
Sales revenue	6,218	8,175	10,415	18,028	31,654
<i>growth over pcp</i>	-66%	31%	27%	73%	76%
EBITDA	(5,240)	(6,989)	(4,561)	387	7,827
Dep'n and amort'n	(666)	(879)	(283)	(215)	(215)
EBITAg	(5,907)	(7,868)	(4,844)	172	7,612
Goodwill amortisation	0	0	0	0	0
EBIT	(5,907)	(7,868)	(4,844)	172	7,612
<i>growth over pcp</i>	-687%	-33%	38%	104%	4314%
Net interest expense	610	200	200	200	200
Pre-tax profit	(5,297)	(7,668)	(4,644)	372	7,812
Tax	0	0	0	0	0
<i>Effective tax rate</i>	0%	0%	0%	0%	0%
Preference dividends	0	0	0	0	0
Minorities	(9)	0	0	0	0
Lodge adjustments	0	0	0	0	0
Lodge adj profit	(5,297)	(7,668)	(4,644)	372	7,812
Reported Net Profit pre-adj.	(5,297)	(7,668)	(4,644)	372	7,812
Adjustment	0	0	0	0	0
Reported net profit	(5,297)	(7,668)	(4,644)	372	7,812

Cashflow (\$T)

Year ending Jun	2012	2013F	2014F	2015F	2016F
EBIT	(5,907)	(7,868)	(4,844)	172	7,612
Net interest paid	610	200	200	200	200
Dep'n and amort'n	666	879	283	215	215
Tax paid	0	0	0	0	0
Gross cash from op'ns	(4,631)	(6,789)	(4,361)	587	8,027
(Inc) / dec in w k'g cap	416	(210)	425	486	1,088
Inc / (dec) in Other Liab.	1,108	0	0	0	0
Other	(4,567)	0	0	0	0
Operating cashflow	(7,674)	(6,999)	(3,936)	1,073	9,115
<i>growth over pcp</i>	-444%	15%	44%	127%	749%
Investing cashflows					
Capital expenditure	296	(100)	(100)	(100)	(100)
Asset sales	0	0	0	0	0
Investments	0	0	0	0	0
Divestments	0	0	0	0	0
Other	196	0	0	0	0
Financing cashflows					
Net equity raised	10,902	0	0	0	0
Dividends paid	0	0	0	0	0
Chg in loans	0	0	0	0	0
Other non-op flow s	126	0	0	0	0
Net chg in cash	3,847	(7,099)	(4,036)	973	9,015

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Recommendations are assessments of each Lodge Partners Analyst's view of potential total returns over a 1 year period.

Expected total Return is measured as (capital gain (or loss) + dividend)/purchase price

We have divided our recommendations into three main categories:

Buy: Expected Total Return in excess of 15% over a 1 year period.

Hold: Expected Total Return between 0% and 15% over a 1 year period.

Sell: Expected Total Return less than 0% over a 1 year period.

Analyst Verification

I verify that I Marc Sinatra, have prepared this research report accurately and that any financial forecasts and recommendations that are expressed are solely my own personal opinions. In addition, I certify that no part of my compensation is or will be directly or indirectly tied to the specific recommendation or financial forecasts expressed in this report.

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