

## **BUY A\$0.21**

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## **GTG Company Data**

Code	ASX:GTG; NASDAQ:GENE
Price	AUD0.21
12 month price target	AUD0.57
Implied return	171%

 Shares on issue
 404,605,152

 Market capitalisation
 AUD85m

 12 month price range
 AUD0.02 – 0.28

 ASX Monthly Turnover
 10.5m

 NASDAQ Monthly Turnover\*
 117m

\* Given in equivalent GTG shares; GENE ADRs 1:30 GTG shares

Financials				
Yr to 30 June	2010A	2011E	2012E	2013E
Revenue	9.8	21.5	17.7	36.8
COGS <sup>*</sup>	2.7	2.8	3.7	6.9
Expenses*	16.5	17.7	10.4	14.2
Profit (before tax)	-9.4	1.0	3.5	15.7
Profit (after tax)*	-9.4	1.0	3.5	15.7
Earnings per share**	-0.025	0.002	0.008	0.039
P/E	-	105	26.3	5.4

\*AUD millions; "AUD

#### **Board of Directors**

Sidney Hack	Chairman
Dr Paul MacLeman	CEO
Huw Jones	Non-Executive Director
Dr Malcolm Brandon	Non-Executive Director
Tommaso Bonvino	Non-Executive Director

## **Major Shareholders**

Mervyn Jacobson 37.3%



Source: Iress Market Technology

# **Genetic Technologies (GTG)**

## Initiating Coverage Report

Genetic Technologies Limited is an Australian Securities Exchange (GTG) and NASDAQ (GENE) listed molecular diagnostics company. The Company also retains a substantial Intellectual Property (IP) Portfolio from which it generates sizeable revenues.

GTG offers an attractive proposition for investors looking for exposure to a company that has high growth potential, with existing revenue streams that provide downside risk mitigation.

The Company is two years into a five year strategy to develop GTG into a world class diagnostics and cancer management business. Lodge expects the Company to generate AUD21.5 million in revenues in FY11 and **record the first in a succession of increasing profits**. We expect the recent launch of the company's lead product, BREVAGen<sup>TM</sup>, in the US to add significantly to revenues from FY13 and profit in FY14.

Historically, GTG has generated the majority of its revenues through its global IP licensing program and its Australia Pacific genetic testing operations. The licensing program has generated more than AUD65 million to date.

In 2009, GTG restructured its Board and new CEO Paul MacLeman began assembling an impressive management team. The Company is now focussed on maximising the revenue from its IP portfolio and its cancer diagnosis and management strategy.

Going forward, we expect the Company to add to its cancer diagnosis and management franchise via M&A, particularly in the area of breast cancer. GTG's acquisition of BREVAGen<sup>TM</sup> for ~AUD1.1 million in 2010 was astute and the current environment is likely to present further acquisition opportunities.

## Analysis:

**GTG** has been streamlined over the past two years, with the injection of quality management and a clear focus now evident. Prior to the acquisition of BREVAGen<sup>TM</sup>, the company's major asset was its IP portfolio covering noncoding regions of DNA and genetic mapping.

GTG has now moved to maximise the value of its IP through formal assertion suits, where respondents are grouped together and sued at the one time in the US. Based on remaining targets, assertion of its IP rights over two of its key patents could yield more than AUD\$100 million in revenues over the coming years, with revenues from other patents, as yet, untargeted.

We expect IP generated to be used for acquisitions, further development and roll out of new molecular diagnostic products. This area provides an exciting opportunity with predecessor companies having done the hard yards in terms of market preparation. To provide an example of the revenues available in this area, the main products of Myriad Genetics (market cap: USD1.95b) and Genomic Health (market cap: USD735m), generated revenues of USD320 million and USD176 million in their last full year results, respectively.

Quality management leads to quality decisions and actions and, on this basis, GTG is clearly headed in the right direction.

#### Recommendation:

We believe GTG's management has positioned the company well to significantly increase shareholder wealth. We initiate coverage on GTG with a BUY Recommendation and a 12-month price target of AUD0.57 per share.

Lodge Partners Pty Ltd 1 Monday, 04 July 2011

## **Background**

Genetic Technologies (GTG) was founded in 1989 to exploit intellectual property (IP) developed around what, at the time, was termed junk DNA.

"Junk" DNA refers to the large expanses of DNA that occur between the sections of DNA that encode genes. As the name implies, it was originally thought that junk DNA was of no use in a biological sense and that it existed simply to hold the genes together into a chromosome.

It is now known that "junk" DNA performs numerous roles that allow a cell to function, such as helping to regulate the expression of some genes. Now the term non-coding is used to describe the DNA once known as junk.

'Junk' DNA has real value

As it turned out, not only was non-coding DNA of use to the cell, but also of commercial use to a number of companies, such as Monsanto and Syngenta, who use sections of non-coding DNA in producing their varieties of various food crops and animals. Companies such as Myriad and LabCorp use it in medical testing, while companies such as Sequenom and Applied Biosystems use it for genetic analysis

In 2000, GTG became a listed company on the ASX via the corporate shell of Duketon Goldfields Limited.

In addition to its IP covering non-coding sections of the genome, GTG has been involved in a range of activities over the years, spanning routine genetic testing through to commercial research projects, such as developing a device to sample foetal cells from the cervix for pre-natal testing.

Since listing, GTG has run at an operating loss, surviving on licencing deals and a single capital raising (2005). However, since the appointment of Dr Paul MacLeman as CEO in mid 2009, GTG has become a progressively more focused company, intent on monetising the value within its noncoding DNA IP and expanding the range of diagnostic testing it offers under the banner of cancer diagnosis and management. The acquisition of the BREVAGen<sup>TM</sup> test for breast cancer from Perlegen Sciences early in 2010 has the potential to be a company making purchase.

The first of what we believe will be a string of increasing profits

On January 28<sup>th</sup> 2011, GTG announced a maiden profit of AUD4.3 million for the half-year ending December 31<sup>st</sup> 2011.

## **Valuation**

We have valued GTG by breaking up the business into three segments. These segments are the company's IP portfolio, BREVAGen<sup>TM</sup> and existing historical operations. Values for the IP portfolio and BREVAGen<sup>TM</sup> have been derived using discounted cash flow methods. A value for the existing historical operations has been derived based on the comparison of revenue multiples with other listed Australian businesses.

Assumptions used in the DCF models are as follows:

#### General Assumptions

- 15% discount rate
- AUD1 = USD1
- 30% corporate tax rate

#### IP Portfolio

- USD7.25 million per year in licensing revenue from patent '179 from 2012 to 2015
- USD1.84 million per year from previous licensing transactions to 2015
- USD10 million per year in licensing revenue from patent '762 from 2013 to 2021
- USD4 million per year in licensing revenue from the patent estate acquired from Perlegen Sciences from 2014 to 2027
- Commissions payable on licensing revenues of 15%

## BREVAGen<sup>™</sup>

- Sales commenced in June 2011
- Effective BREVAGen<sup>™</sup> price of \$426
- Sales of 6,000 tests in FY12 and 27,600 in FY13
- Max Sales of 300,000 tests in FY18 and FY19, decreasing at a rate of 15% thereafter
- Cost of goods sold of 35%

Table 1 details the revenue multiples of three Australian listed healthcare companies and applies the average multiple to GTG's existing operations.

Table 1. Revenue multiples applied to three listed Australian healthcare companies.

•	0040 D (AUD)	Market Capitalisation	BB 165 - 1
Company	2010 Revenue (AUD)	(AUD)	Multiple
Primary Healthcare (PRY)	1.3 billion	1.6 billion	1.26
Ramsay Healthcare (RHC)	3.4 billion	3.7 billion	1.08
Sonic Healthcare (SHC)	3.3 billion	4.7 billion	1.43
		Average Multiple	1.26
GTG existing operations	5.1 million	Estimated Value: <b>6.4 million</b>	

Tables 2 looks at the value derived for each of the GTG business segments in question and provides a total value for the company.

Table 2. Values derived from each GTG business segment and the overall valuation.

GTG Segment	Value (million AUD)
IP Portfolio	72.0
BREVAGen <sup>™</sup>	115.4
Existing operations	6.4
Cash (as at March 2011)	7.2
Total	201.0

As can be seen in terms of market capitalisation, we have arrived at a value for GTG of AUD201.0, which equates to a share price of AUD0.50 per share and a 12-month price target of AUD0.57 per share.

## The values generated by our analysis are solid

Very significant value remains in the IP portfolio

That remaining value of the IP portfolio is slightly higher than the licensing fees collected to date does seem a little illogical from the standpoint of the age of the two main patents (one has expired and the other expires in 2015), GTG has really only been aggressively asserting its rights to these patents since early last year. As is discussed later, their strategy for asserting these rights has been working extremely well and plenty of time remains to pursue infringement of these patents. Also, the acquisition of the Perlegen assets provides further patents over which GTG can assert its rights.

BREVAGen<sup>™</sup> was a 'bargain'

In terms of BREVAGen<sup>TM</sup>, available data indicates GTG got what is best described as a bargain. Only the purchase price of just over USD1 million would suggest otherwise. Investors saw enough in Perlegen Sciences to invest over USD300 million in it and BREVAGen<sup>TM</sup> has all of the characteristics of a successful diagnostic (impressive clinical trial results, provision of clear actionable information to the physician, economic effectiveness data, etc).

Upside remains in the valuation of the existing operations

Valuing GTG's existing operations is a little more difficult because breaking out indirect costs associated with those operations isn't easy. Having said that, by applying revenue multiples associated with large diverse healthcare companies, we have probably underestimated the value of these existing operations. The primary reason for this is that the margins associated with a specialist healthcare company should be higher than those of general healthcare companies on the basis that specific expertise would add value. Given the value of GTG's primary assets, an undervaluation of the existing operations would not have a significant impact on the overall valuation.

## The Opportunity

Two-years into a fiveyear plan Change has been the norm at GTG since Paul MacLeman's appointment to the role of CEO, with the implementation of a five-year plan to transform GTG into a company with a focusing on diagnosis and management of cancer. **The company is now two-years into this plan**.

**Management has been overhauled**, with only one pre-MacLeman manager remaining, while five new managers have been appointed. In general, the business itself has been better defined and focused with particular attention and effort being put into two areas.

Licencing revenues to continue for approx. 15 years

One of the areas concerned is GTG's intellectual property portfolio and, in particular, two patents families that relate to non-coding DNA. Numerous companies, research institutes and other groups have long been infringing these patents. In the past, GTG has been sporadic in terms of asserting its patents rights and negotiating licensing deals. This has changed under current management, who have been moving aggressively to assert GTG's patent rights in the US and Europe. The net result has been a dramatic increase in licensing revenues culminating in GTG's maiden half-year profit to December 2010 and likely maiden full-year profit to June 2011. We believe licencing revenues from GTG's intellectual property portfolio will continue for approximately 15 years.

The use of molecular diagnostics in cancer is expected to grow at 34% per annum

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Market environment favours acquirer's

BREVAGen<sup>™</sup> sales have commenced

Improvement of the business has occurred on every level of GTG

The second area into which GTG is putting considerable effort is in building an arm of the Company that is dedicated to the diagnosis and management of cancer. Under this umbrella, a specific focus on breast cancer in particular is emerging. The reasons for building a capability in this area are numerous. While personalised medicine is in its infancy, its application in the area of cancer is further progressed - genetic testing of individuals and testing of tumours is becoming common place, with the early companies in the area having achieved the difficult goal of physician education and acceptance. This has led to the expectation that the use of molecular diagnostics in the area of oncology will have a compound average growth rate (CAGR) of 34% out to 2014 (TSG Partners; Scientia Advisors). While the growth rate is expected to be high, many of the companies who started developing tests for this area will not be the ones who take them to market. The Global Financial Crisis (GFC) has made capital scarce for medical technology companies and many have found themselves either in financial trouble or treading water. The prevailing conditions are optimal for an acquisitive company with a secure revenue stream to acquire good, at or near market, diagnostics for a fraction of their development cost. Obviously, from the base of its existing operations GTG is in a solid position to enter this space with the revenue from its IP estate providing the means. Importantly, the move also opens up the US market to GTG, providing the company with growth opportunities it has not previously had, such as in the proven market of women's health.

GTG's move into the US will initially be driven by sales of its BREVAGen™ test. The test is designed to assess breast cancer risk in women who do not carry either high risk breast cancer genes, BRCA 1 and 2. Initial sales in the US have commenced, with the first US samples being received and tested recently, and the product's formal launch just announced. Molecular diagnostics for known breast cancer genes and for determining the best therapy for breast cancer patients have done very well in the US (discussed in detail later). As with any new product, though, risk is relatively high and, despite the extensive market research carried out regarding BREVAGen™, it may take a little while to get the marketing of the test right.

While GTG's focus on increasing licensing revenues and developing a cancer diagnosis and management business are plain to see, a great amount of work has gone into the business which is not as easily identified by investors. Principally, this effort has gone into expanding the Company's existing quality system into a company-wide quality system. While it is usual for diagnostic businesses to have quality frameworks under which their testing operations fit, GTG has essentially expanded its quality system to include the assessment of new projects and the rollout of new products, including the identification and quantification of the risks faced and opportunities they create. The amount of planning and preparation that has gone into the roll out of BREVAGen<sup>TM</sup> is nothing short of outstanding in our opinion.

We expect the evolution of GTG into a molecular diagnostics company to continue, with the addition of further technologies/businesses in the cancer diagnosis and management space. It is also likely that some of GTG's existing businesses and activities that no longer fit within the company's overall strategy will be divested. **Expansion in the direction of the US market is likely to continue**, although this expansion will initially be tied to the success of BREVAGen™ and the speed with which that success comes.

Just as a performance car is dependent on the talent of its driver to distinguish it from other cars, GTG is highly leveraged to the quality of its management. For continued success, GTG's management team will need to carefully steer the company through what is a major period of change. The GFC has meant that the opportunities are out there in terms of assets. The management team needs to identify which of these assets truly represent quality and move to acquire them at an appropriate price and execute their entry into the market.

First-rate management acquiring first-rate technology

There is an old saying in the venture capital industry that it is better to have first-rate management and a second-rate product rather than vice-versa. Over the last two years, GTG has built a first-rate management team, who, in turn, have brought in a first-rate product in BREVAGen<sup>TM</sup>.

While GTG will appeal to investors with a high risk/high return profile, it should be noted that the company's existing royalty stream from the non-coding DNA patents and pathology business provide significant downside protection.

## Management

Over the course of the last couple of years, GTG has changed considerably. No more so than in its management. We believe that management is the key to GTG's future. Hence, where we would normally examine management later in a research note, we believe management needs to be first and foremost in the mind of an investor when considering GTG. GTG's management comprises the following individuals:

Well credentialed and highly respected CEO

**Dr Paul MacLeman**, *Chief Executive Officer*, BVSc, MBA, Grad Dip Tech Mgt, Grad Cert Eng, FAICD. Dr MacLeman was most recently CEO of Hatchtech, a spin-out of the University of Melbourne, primarily focused on the development of a new treatment for head lice. He built Hatchtech from a research stage company to one with a product in international phase II trials. Prior to his appointment at Hatchtech, Dr MacLeman was Chief Operating Officer at the ASX listed biotech Imugene Pty Ltd (ASX:IMU). Importantly, he was Vice President at Agenix Ltd (ASX:AGX). Agenix is one of Australia's oldest biotechnology companies. Until recently, it was strongly focused on diagnostics. Agenix developed the d-dimer test which went on to become the industry standard in the initial workup of patients suspected to have deep vein thrombosis and/or pulmonary embolism. Like CSL (ASX:CSL) and Amrad, Agenix employed a number of people who have gone to take leading roles in other Australian biotechnology companies. Dr MacLeman has also held roles in investment banks, focusing on life science companies, and several start-ups, including Hatchtech mentioned above.

**Thomas Howitt,** Chief Financial Officer and Company Secretary, BCom, ACA, FTIA, ACIS, AICPA. Mr Howitt has been with GTG since 2004. He has extensive experience in the roles of CFO and Company Secretary having worked for several local and overseas listed entities, including technology development companies. In particular, Mr Howitt has extensive experience in capital raisings, due diligence, with a focus on technology companies and development, patenting and commercialisation of technologies. Importantly, he has previously been responsible for a number of significant acquisitions. Past employers include Molopo Australia Ltd. (ASX: MPO), Hedong Energy Inc.(VSE: HE), Lakes Oil NL (ASX: LKO) and Intermoco Ltd. (ASX:INT).

Alison Mew, Chief Operating Officer, MSc(Hons). Ms. Mew has a solid reputation in the area of organisational change management. Previously, she held operational roles in the pharmaceutical, Bioscience and Animal Health Divisions of CSL for over 13 years, gaining significant exposure to diagnostics during that time. Prior to joining GTG, Ms. Mew was a consultant providing advice regarding strategy and operational matters to companies involved in life science product development. Other employers have included Pitman Moore NZ Ltd and Wellcome Biotechnology Ltd.

**Dr David Sparling,** Vice President Legal and Corporate Development, BVSc Hons, LLB (Hons) Grad Dip Corp Governance. At GTG, Dr Sparling's role at GTG is to drive expansion primarily through mergers and acquisitions & contribute significantly to strategy development. Prior to his appointment at GTG, Dr Sparling was chief operating officer at Solbec Pharmaceuticals, a company developing treatments for cancer and dermatological conditions. He has significant experience in the area of diagnostics gained while he was commercial counsel for Agenix Ltd. In addition to his position at GTG, Dr Sparling is Chairman of FYI Resources Ltd (ASX: FYI).

**Gregory McPherson**, *Vice President Sales and Marketing*, BA, BBus. Mr McPherson has over 20 years experience in Marketing and Sales. He has a reputation for managing multi-channel revenue streams through management accountability. The diversity of Mr McPherson's experience is highlighted by having worked for companies such as Xerox, Mitre 10, Spotlight, Whirlpool and, importantly, Symbion Health.

Proven Head of American Operations Lewis Stuart, General Manager & President, Phenogen Sciences Inc, BA, MBA. Mr Stuart was hired specifically to lead GTG's US subsidiary Phenogen Sciences and to lead the rollout out of GTG's breast cancer risk test, BREVAGen™ in the US. With almost 30 years experience in Sales and Marketing in the pharmaceutical and life science industries, Mr Stuart brings with him a wealth of experience to Phenogen. He comes to Phenogen from CV Therapeutics, where he was Senior Vice President in charge of Commercial Operations. Mr Stuart was responsible for the launch of CV's lead product and is credited with playing a major role in CV's growth from USD300 million company until Gilead's acquisition of it for USD1.5 billion. At CV, Mr Stuart's responsibilities covered sales, marketing, medical affairs, managed care, operations and investor relations. Mr Stuart built CV's 325 person commercial team and related infrastructure. Prior to CV, Mr Stuart

held several senior sales and marketing positions in the US and Europe, including stints with Bristol Myers Squibb and Agouron Pharmaceuticals (now a subsidiary of Pfizer).

Ivan Jasenko, Quality and Regulatory Manager, BA. Mr Jasenko has over 10 years local and international biopharmaceutical experience ranging from R&D & product development to quality and regulatory roles in both human and animal health. At GTG, he was responsible for gaining CLIA (Clinical Laboratory Improvements Act) accreditation for the Company's Fitzroy laboratory, enabling it to provide diagnostic services to the US. He maintains responsibility for the Company's compliance in respect of CLIA and the other relevant regulatory bodies that a company such as GTG must satisfy. Most recently, he has held senior positions with Intervet – Schering Plough Animal Health and the New Zealand Company ICPBio.

Excellent, focused, appropriately incentivised management

With the exception of Mr Howitt, GTG's management team has been handpicked and appointed in the post-MacLeman era. Importantly, each individual appears to have been given a clear, well-defined role to play in the Company's future. While the GFC has had a role to play in GTG finding inexpensive quality products to acquire, it has also helped in the recruitment of quality staff. Lewis Stuart is particularly well qualified to lead GTG's foray into the North American market, having demonstrated the ability to build product sales from scratch several times. While the quality of management is high, 2010 remuneration for the executives was not in any way excessive; coming in at AUD1.2 million for 2010 (excludes salaries of Stuart and Jasenko). All key executives have been granted between 1.5 million and 3.6 million options exercisable at 4.5 cents per share. Consequently, it can be concluded that GTG's managers are appropriately incentivised to build value in GTG.

#### **GTG – The Business**

GTG can currently be viewed as a company with three core segments. Those segments are:

Three core business segments

- 1. Intellectual property licensing
- 2. Long-term stable operations (includes genetic testing, forensics, animal testing)
- 3. Cancer diagnosis and management

Long-term stable operations refer to GTG's paternity testing, forensic testing and animal testing services, as distinct from the testing GTG performs in the cancer diagnosis and management realm. There are various other segments or businesses that operate under the GTG banner, such as two product development projects. While some of these are discussed below, they can generally be considered as non-core activities and they are, at best, likely to have a limited lifespan within GTG.

#### **Licensing Activities**

GTG's original patent estate consists of a suite of patent families, the most important of which are the '179 patent and the '762 patent. Both patents relate to the use of non-coding DNA to detect alleles of nearby genes. An allele refers to the specific DNA code found at the site of a gene. A gene may have various alleles, which, in turn can result in various traits, such as blue eyes.

The priority date (generally, the date on which a full patent application is submitted) for each of these two patents varies from country to country, consequently so do the expiration dates of the patents. In the US, the '179 patent has expired, while the '762 patent doesn't expire until 2015.

Patent expiry doesn't preclude assertion for past infringements

The expiry of a patent, however, doesn't preclude a law suit for past infringement. In the US, owners of patents can sue for infringement for up to six years after patent expiry. In Europe, the period of time after expiry in which suits can be brought varies from country to country, although in most countries it is between 4 and 6 years.

Consequently, in the US for example, GTG will be able to sue companies for the past infringement of the '179 patent until 2016 and the '762 patent until 2021.

To date, GTG has granted more than 50 licenses in return for a total of AUD65 million. The licenses currently granted will generate a total of a further AUD9.2 million to 2015.

Formal patent assertion strategy

In February of 2010, GTG adopted a formal strategy for monetizing the value of its '179 and '762 patents in the US. The strategy involves grouping infringing parties together and bringing a law suit in an appropriate court. There were nine counterparties to the first suit, which was successfully concluded by GTG in mid-April with none of the counterparties proceeding to trial. A second assertion suit was filed in January 2011 and active settlement discussions continue between the parties. A third suit was recently filed naming ten parties and a fourth suit is in the planning stages.

There are some large companies cited in the third infringement suit, including GlaxoSmithKline PLC and Pfizer, Inc. It seems reasonable to conclude that GTG could expect at least \$100 million in coming years from licencing with the ultimate number likely to be determined, at least to some extent, by the speed with which they can act.

GTG's strategy in Europe has and remains to engage individual infringers on a case by case basis, due to the fragmented nature of European market.

Patents acquired from Perlegen will create further licensing revenues In its acquisition of the majority of the assets of Perlegen Sciences Inc, GTG has gained ownership of further intellectual property relating to non-coding DNA. The patent estate acquired is solid and it is clear that others are infringing the patents. The earliest of these patents expires in 2021, leaving plenty of time for GTG to assert its rights over them and, ultimately, extract significant value.

## **Stable Operations**

The stable operations segment of GTG has produced just over **\$3 million in gross profit** for the Company for each of the last two years.

The services they offer can be broken down into the following categories of testing:

- **Medical**: includes testing a range of genetic diseases including Down's syndrome, multiple sclerosis, muscular dystrophy and epilepsy among others.
- **Paternity**: this category refers to paternity testing in its broadest sense, where samples may not only come from the parents, but from siblings, grandparents and other relatives
- Forensic: routine to more complex tests.
- Animal: Largely focused on dogs. Testing services range from genetic diseases, to coat colour identification and breed identification
- Plant: Provider of plant DNA sequencing and analysis in conjunction with Agriculture Victoria Services Ltd.

**Mature business** 

The company itself describes the business as mature and there are likely to be few easy growth opportunities. GTG already believes it has 50% of the Australian & New Zealand paternity testing market. In terms of canine testing GTG provides genetic testing to most of the Pacific rim canine clubs. In short, this segment of the business is likely to show only modest growth of 2-5%.

Positive news on the forensics front

Recently, there was some positive news on the forensics front. GTG provides a fully accredited forensics service and is currently contracted by the New South Wales police force to perform "volume" (simple) testing on their behalf. GTG recently signed a one year contract to perform complex volume testing in addition to the testing they have been performing.

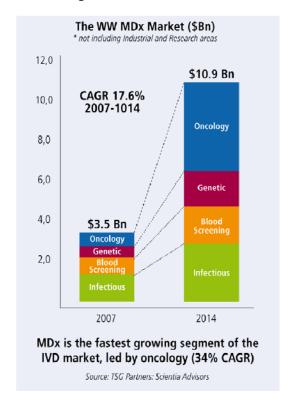
While this news may provide the impetus for other domestic police forces to follow suit, the outsourcing of forensics work is as much a political issue as it is one of cost efficiency. Should other police forces follow-suit a nice business could be the result. Nonetheless, it is unlikely to prove an area of explosive growth for GTG.

#### **Cancer Diagnosis and Management**

While the cancer diagnosis and management segment of the business could easily be considered part of the medical testing, GTG has carved it out primarily for reasons given earlier in this note. A main driver, however, is the growth that is expected in this area over the next few years, as illustrated in figure 1.

Lodge Partners Pty Ltd 7 Monday, 04 July 2011

Figure 1. Worldwide Molecular Diagnostics Market.



GTG is building a suite of products to enable it to support clinicians from the prevention of cancer through to monitoring patients for the return of previously treated cancer.

GTG currently offers testing for:

GTG already offers a wide variety of molecular tests

- Hereditary breast, ovarian, colorectal cancers
- Non-familial breast cancer risk
- · Distinguishing between various forms of lung cancer
- Determining the origin of metastases (ie where the primary tumour is located)
- Selecting and monitoring therapies for colon, lung and gastric cancer

GTG is also developing tests in house which fall under the aptly named banner "laboratory developed tests". These tests, for the oncogenes (a gene that when mutated can cause cancer) KRAS, BRAF and the EGFR, can be useful when determining a cancer patient's prognosis and may provide useful information in terms of how to best treat a particular cancer.

Most pathology laboratories tend to be big with a defined set of departments, such as biochemistry, microbiology and haematology. As such, it is worth asking the question whether there is a rationale for a company to be a standalone cancer diagnostics and management laboratory. In our view, the answer to this question is yes. The reasons are as follows:

It is a defined subset of medical practitioners that are likely to use these services. These are obstetricians and gynecologists with an interest in genetics/cancer treatment. A specialist testing laboratory, such as GTG, is in a position to develop a relationship with these doctors, build their trust and educate them about existing and new diagnostics in a way that larger pathology laboratories are unable to.

Cancer diagnosis and management is an area where a specialist molecular diagnostics company can add significant value

This is particularly important in an area that is complex and rapidly evolving. Many tests give results which ultimately end-up as a binary result. Oncology diagnostics, however, is heading in a direction where results are much more complex, such as the level of cancer risk conferred by a particular set of genes or how best to treat a cancer expressing a particular pattern of genes. The laboratory needs to be able to explain the results to the doctor and the doctor must have enough faith in the results to act on them.

The crux of the issue is that the use of molecular diagnostics in the diagnosis and treatment of cancer is evolving much more rapidly than the guidelines for treatment issued by various health related bodies. This, in turn, is due to the needs of cancer patients and those at-risk of cancer, as

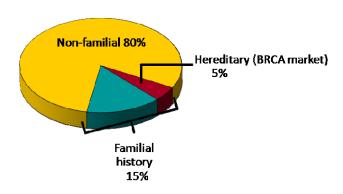
well as the speed with which science is accumulating knowledge about cancer. Health bodies tend to be very conservative when it comes to issuing treatment guidelines with vast quantities of data required before a diagnostic is included in them. To provide an illustrative example one of the breast cancer diagnostics discussed later, Oncotype Dx, had been on the market for over three and a half years and was generating USD60 million in revenues before it was formally included in the major breast cancer treatment guidelines. It is within this time between launch of a test and its incorporation into clinical guidelines where the guiding-hand of the specialist molecular diagnostic company can be of great help to physicians with patients in need.

#### BREVAGen™ - The Test

The newest test in GTG's portfolio is BREVAGen™. It is a test designed to determine breast cancer risk in women who do not carry either of the BRCA genes. **Overall, this represents around 95% of women who develop breast cancer.** 

This group can be further spilt into hereditary BRCA negative individuals, representing 15% of breast cancer cases, and sporadic (non-familial) breast cancer, representing 80% of cases (see figure 2). The difference between the two groups is the presence or absence of a clear family history of breast cancer.

Figure 2. Breakdown of breast cancer cases by genetic predisposition.



Adapted from Genetic Technologies Corporate Presentation, June 2011

BREVAGen<sup>TM</sup> is based on the detection of seven single nucleotide polymorphisms (SNPs). An SNP refers to variation in the nucleotide (the building blocks of DNA - adenine, cytosine, guanine, thymine) found in a particular position in the DNA of individuals.

BREVAGen<sup>™</sup> evaluates more incremental increases in breast cancer risk The BRCA genes are essentially all or nothing. If a woman has one of them, their chance of getting breast cancer is vastly increased. Each SNP that BREVAGen<sup>™</sup> detects is associated with a small increase in breast cancer risk. However, the risk associated with each SNP is cumulative, such that if a woman carries several of the SNP's her cumulative risk may be quite high.

BREVAGen™ was acquired from the now defunct Perlegen Sciences. Perlegen had raised more than \$300 million during its lifetime, only to hit problems when it needed to raise capital at the height of the GFC to support rolling the test out into the market. Ultimately, GTG, who was a shareholder in Perlegen, was able to purchase many of Perlegen's assets for a little over USD1 million.

The SNPs used in the BREVAGen™ test were discovered as a result of a large genome-wide association study, where traits, such as cancer risk, are matched with polymorphisms (differences) in study participants' DNA. This data can then be used to calculate odds ratios. An odds ratio is a number that describes a person's chance of developing a disease relative to the overall population.

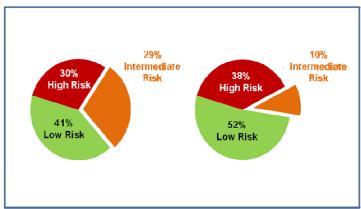
A patient's BREVAGen™ result provides the doctor actionable information

Although in some cases an individual will simply want to know their risk of developing breast cancer, that sort of demand is unlikely to be enough to support the test commercially. To be commercially supported, a diagnostic must produce actionable information to the doctor. That is information the doctor can use to improve the patient's situation. The value that BREVAGen<sup>TM</sup> provides to the doctor (and patient) is an estimate of breast cancer risk which can then be used to determine how intensively the person should be monitored for breast cancer. In addition, women identified by BREVAGen<sup>TM</sup> as being at high risk of breast cancer tend to develop what are termed

estrogen receptor (ER) positive breast cancers. The drug Tamoxifen is very effective at treating ER positive cancers, particularly if they are caught early, and is also suitable for preventive therapy in women at risk of ER positive cancers.

A real world example of the utility of BREVAGen<sup>TM</sup>, comes from a recently published case-control study using the test (Mealiffe et al, J Natl Cancer Inst, 2010). One of the questions examined in this study was the impact of using BREVAGen<sup>TM</sup> to better define the breast cancer risk of study participants who had previously had a breast biopsy. These women are currently classified as being of intermediate breast cancer risk. In figure 3, it can be seen that 29% of women were classified as intermediate risk prior to BREVAGen<sup>TM</sup> testing, but that only 10% remained in that category after testing.

Figure 3. Reclassification of intermediate risk patients using BREVAGen™.



Adapted from Genetic Technologies Investor Presentation, June 2011

Almost two-thirds of intermediate risk women could have their care changed due to BREVAGen<sup>TM</sup>

BREVAGen<sup>TM</sup> testing in this situation reclassifies 64% of intermediate risk patients into the high or low risk groups. The net result is more appropriate surveillance/treatment of patients, with those reclassified as high risk receiving more aggressive surveillance/treatment, while others who are reclassified into the low risk category are released from the burden of intensive surveillance/treatment.

The target market for BREVAGen™ is potentially enormous consisting of every female over the age of 35.

Highly focused initial target market

GTG's initial target market, however, is more modest, focusing on women with a family history of breast cancer who have tested negative for each of the BRCA genes. Based on 2010 National Cancer Institute figures approximately 31,000 cases of breast cancer in the US fall into this category each year. Figure 4 shows how BREVAGen<sup>TM</sup> testing is likely to be incorporated in this market.

The reason for targeting this market first is that they are the group most in need of information regarding their genetic status and breast cancer risk. The specialist doctors they are seeing are also the ones most capable of understanding the clinical utility of BREVAGen™ and they are highly motivated by the need of their patients.

Very large post-biopsy market

The second target population is those women who have had a breast biopsy as a result of a positive mammogram or MRI and for whom a diagnosis other than normal or cancer has been made. It is this group on which figure 3 is based. Figure 5 shows how BREVAGen<sup>™</sup> testing is likely to be incorporated in this market. According to GTG, of the 1.6 million breast biopsies done in the US each year, 65% present findings other than normal or cancer. This creates a large additional market of approximately one million women annually who could benefit from BREVAGen<sup>™</sup> testing.

Figure 4. Incorporation of BREVAGen™ testing in evaluation of patients with a strong family history of breast cancer

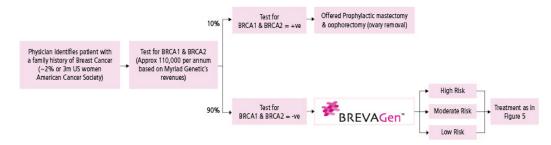
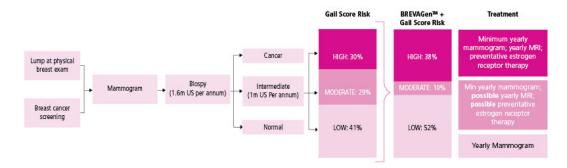


Figure 5. Incorporation of BREVAGen™ testing in evaluation of patients with intermediate breast biopsy results



## BREVAGen<sup>™</sup> - Market Acceptance

There are three factors that we believe will drive market acceptance of BREVAGen<sup>TM</sup>.

BREVAGen<sup>™</sup> fits with existing cancer management guidelines

The first is that BREVAGen™ has been designed to fit in with the American Society of Clinical Oncology and American Cancer Society Guidelines for estimating breast cancer risk.

Currently, the guidelines recommend estimating a patient's risk using the Gail Model. The model uses the answers to a series of seven personal questions, such as age at first live birth, to estimate a woman's risk of developing invasive breast cancer. It was developed based on the results of a very large screening study and has since been validated. The output from the model is a percentage chance of developing breast cancer in a woman's lifetime (e.g. 25%) and in the next five years (e.g. 1.5%). The information is used in the following way: If, for example, a woman's 5-year risk of breast cancer is greater than 1.66%, the American Society of Clinical Oncologists guidelines indicate that a patient may be offered preventive estrogen receptor therapy.

The model, however, collects limited genetic information, is influenced by how well a woman's family history has been documented and is unlikely to detect complex genetic factors that influence breast cancer risk.

Existing risk estimate is simply multiplied by the BREVAGen<sup>TM</sup> result show

Based on the SNPs detected, BREVAGen<sup>TM</sup> determines a woman's odds of developing breast cancer relative to the average population (specifically speaking, the white female population). A person at average risk will have a BREVAGen<sup>TM</sup> risk stratifier of one, while someone with twice the risk will have a stratifier of two. Because the Gail model and BREVAGen<sup>TM</sup> results have been shown to be largely independent, it is possible to multiply their Gail risk by their BREVAGen<sup>TM</sup> risk stratifier to arrive at an adjusted 5-year and lifetime risk. The result can be very important. A patient with a five-year Gail risk of 1.2% and a BREVAGen<sup>TM</sup> risk stratifier of 1.5 ends up with an integrated 5-year risk of 1.8% and is a candidate for preventive estrogen receptor therapy.

BREVAGen<sup>™</sup> has been validated in a large study published in a highly regarded journal

Like the Gail model, **BREVAGen<sup>TM</sup>** has also been validated in the clinical setting. The case-control study mentioned above did not only show that BREVAGen<sup>TM</sup> benefited intermediate risk patients, but all patients. This study involved a significant number of participants (n=3300) and was published in the highly regarded Journal of the National Cancer Institute. While physicians will always be influenced by relationships and general marketing efforts, a solid peer-reviewed article in a quality journal carries a very significant amount of weight.

Finally, physicians are sensitive to the cost of tests they ask their patients to take and it is important that those costs be put in a form which they can understand. In these situations, the common metric used is cost per quality adjusted life year (QALY; a measure of disease burden

The cost effectiveness of BREVAGen<sup>™</sup> has been demonstrated by a well respected group

based on the quantity and quality of life lived). In 2010, researchers published an abstract at the American Society of Clinical Oncology Annual Meeting in June of 2010, demonstrating that BREVAGen™ was associated with a cost of USD3,800 to USD7,500 per QALY. While this study was done by computer modelling, rather than by assessing hard data, BREVAGen™'s cost effectiveness is impressive. In general, a medical intervention is considered cost-effective if it comes in below USD30,000 per QALY. The study was performed by Archimedes, Inc, a firm whose modelling and simulation of healthcare related questions have formed the basis for numerous peer-reviewed publications.

#### Other GTG Businesses

GTG has a range of wholly or partly owned subsidiaries containing various assets. The significant assets held within these subsidiaries have largely already been mentioned. Two subsidiaries, however, do contain research/products that may result in material revenues most likely via a trade sale or licensing agreement. They are:

- RareCellect® a device for obtaining foetal DNA from a cervical sample
   ImmunAid<sup>TM</sup> a project based on the concept of immune system cycling

#### RareCellect

First-line clinical investigation where foetal abnormality is suspected or being screened for involves two tests provided the foetus is, at least, 11 weeks old. These are ultrasound and maternal serum screening. These two tests, however, miss up to 80% of abnormalities.

More definitive assessment of the foetus' state can be gained by direct sampling, either by chorionic villus sampling (sampling from part of the umbilical cord), which can be done between 11 and 14 weeks, or by amniocentesis. Amniocentesis is only suitable for foeti 15-weeks or older. Both of these types of test are invasive and carry risks to both the mother and the foetus, with miscarriage rates as high as 5%. It is this risk that also limits the procedure to women aged 35 and older. Invasive testing is being offered more as an option to women of younger age now, indicating the demand for the information these procedures supply.

A much better way of obtaining foetal cells Due to the invasiveness of chorionic villus sampling and amniocentesis, GTG has developed a device which collects foetal material from the cervix. Additionally, it has developed enrichment methods for preparation of foetal DNA from those samples. Both the device and the enrichment methods are the subject of various patent filings.

GTG believes the device could be commercialised and on market in three to five years and is currently looking to licence/partner the technology.

We believe that this technology, while not a company maker, would be a good fit with a device company operating in the gynaecological/obstetrics area.

## ImmunAid<sup>™</sup>

ImmunAid<sup>™</sup>, a company in which GTG has a 71.7% stake, is developing a method of treatment for various diseases, including HIV and cancer, based on the observation that the immune system turns itself on and off in cycles when a patient has a chronic disease.

ImmunAid<sup>TM</sup> believes by appropriately timing an intervention, such as chemotherapy, a group of immune cells (called T cells) can be activated. Once activated, ImmunAid<sup>TM</sup> believes that the immune cells will attack, for example, HIV infected cells.

This technology has been the topic of a presentation by researchers from the Mayo Clinic, a highly regarded US hospital, at the American Society for Clinical Oncology.

As with, RareCellect<sup>™</sup>, GTG, is looking to others to take the technology further.

## BREVAGen™ - The First Step

It is clear that GTG's near to medium term success will be determined by the success of BREVAGen™. The test was officially launched in the US by GTG's wholly owned subsidiary Phenogen Sciences Inc. on 20 June 2011.

Straightforward process

The overall process for marketing, sample collection, result reporting and fee collection is expected to work like this. The samples (two cheek swabs) are collected by the doctor during a patient visit. The samples are then sent to Phenogen Sciences offices in Charlotte, North Carolina where they are aggregated and couriered to GTG's labs in Melbourne, where testing is performed.

Once tested, the results are electronically dispatched to Charlotte where reports are printed and sent to the referring doctor. The turnaround time is expected to be 12-15 days, which according to market research conducted on behalf of GTG is acceptable to referring doctors (the turnaround time for similar tests conducted in the US is approximately 7-9 days).

**GTG** intends to charge USD945 per BREVAGen<sup>™</sup> test. It has engaged a well established company called Premier Source to handle charging for the test and obtaining reimbursement for it from insurance companies.

Reimbursement will occur via a series of codes termed current procedural terminology (CPT) codes which are maintained by the American Medical Association. Under this system, the insurer is charged according the steps in the BREVAGen<sup>TM</sup> test process rather than for the test itself. For example, the CPT codes will specify a price for DNA extraction, performance of a laboratory method called polymerase chain reaction and report preparation among other things. The collection of individual codes for which insurers will be charged is termed a stack.

Through Phenogen Sciences, GTG has initially hired eight sales representatives who will market the test to doctors in their respective territories. Seven of the eight representatives are located roughly in the eastern third of the US, with one representative operating out of Seattle, Washington. The launch territories have been specifically chosen based on three main criteria. They are:

BREVAGen<sup>™</sup>'s rollout has been very well planned

- CLIA status
- Ease of reimbursement
- Patient clustering

Purchased marketing data has been used to determine the areas where reimbursement for testing is the easiest and where patients likely to have a BREVAGen™ test are located.

Eight of the fifty US states (including New York and California) have additional requirements to those required by CLIA for the performance of diagnostic testing on humans. Eventually, GTG will move to meet these requirements, but, at this stage, they do not see it as a high priority and we agree. As with any new product, the marketing strategy will and should change as real-time marketing data is gathered. It does not make sense to go after markets with higher barriers to entry until you have the strategy right.

Scaling of the business in response to sales is easy

The whole US operation has been set up such that it can be scaled up or down quickly in response to interest in the product. Employment laws in the US allow for the fairly quick dismissal of staff with few costs, such that underperforming staff do not remain a liability for long. Additionally, base salaries for sales representatives in the US tend to be lower and performance bonuses higher, which further help to scale operating costs with commercial success.

Overall, we believe that GTG's strategy for US market entry is extremely well put together, with the appropriate controls put in place to manage risk.

## BREVAGEN<sup>™</sup> – Market Entry Eased by Predecessors

As stated earlier, cancer is ahead of the curve in terms of the application of personalised medicine. Two companies, in particular, Myriad Genetics and Genomic Health, have led the way.

Myriad Genetics (NASDAQ: MYGN; market capitalisation: USD2 billion) produces a range of tests for a range of cancers, but is best known for their BRACA test which produces just under 90% of the company's revenues. BRACA revenues for fiscal 2010 were USD320 million. Revenues for the first three quarters of fiscal 2011 were USD260 million, leading to an expectation that revenues from the BRACA test will have grown between approximately 6%-10% on a year on year basis.

Generating these sorts of revenues did not happen quickly for Myriad given their BRACA test was launched in 1996. The issue, however, was not the quality of the test, but one of market acceptance. It was only a few years earlier that the first of the genes responsible for hereditary cancer was cloned and it takes a while for research to be translated into commercial success, particularly when you are on the leading edge of the technology curve.

The market for breast cancer molecular diagnostics is proven

Genomic Health (NASDAQ:GHDX; market capitalisation: USD753 million) focuses on developing diagnostics that improve treatment decisions. Its main product is the Oncotype Dx breast cancer assay. While the company has other products on the market, such as their Oncotype Dx colon cancer assays, it derives nearly all of it revenues from the breast cancer test. Genomic's revenues have been steadily growing. They were USD150 million and USD176 million for calendar 2009

and 2010, respectively. Revenues of just under USD50 million for the first quarter of this calendar year put them on track for a 2011 result of over USD200 million.

Genomic has achieved these revenues in just over 7 years since market launch, suggesting that the market is now more comfortable with the use of personalised medicine in cancer diagnosis and treatment than it was when Myriad launched its BRCA test fifteen years ago. This is despite the quite profound differences in the nature of BRCA testing and Oncotype Dx. We expect this to augur well for BREVAGen<sup>TM</sup> acceptance and sales.

Predecessor companies have prepared the market for BREVAGen™

Genomic Health is a pretty good comparator to GTG. While their two respective tests differ in the information they provide, both tests represent next generation cancer tests.

Sales of Oncotype Dx commenced in 2004. Sales were initially slow, but began to increase in 2005. This coincided with the release of economic data supporting the cost effectiveness of Oncotype Dx. Further events that triggered an increase in sales include when the US Medicare agreed to provide a rebate for the test (insurer's tend to follow Medicare's lead) and formal inclusion of Oncotype Dx in the treatment guidelines of professional bodies.

BREVAGen<sup>™</sup> is in a better position than Oncotype DX when it was launched

At launch, BREVAGen<sup>TM</sup> appears to be in a better position than Oncotype Dx was. Oncotype Dx did not dovetail nicely with current clinical guidelines, it had substantially less published evidence to support its use and cost effectiveness data was not yet in place. Thus, we expect sales of BREVAGen<sup>TM</sup> to grow at a faster rate than those of Oncotype DX on a like versus like basis.

BREVAGenTM has a larger addressable market than Oncotype DX

The addressable market for BREVAGen<sup>TM</sup> in the US is also substantially larger than that for BRCA testing and Oncotype Dx. Myriad's revenues suggest it performs around 110,000 BRCA tests per year, while the market for Oncotype Dx is limited to the estimated 207,000 (National Cancer Institute, 2010) new cases of breast cancer in the US and some additional testing for recurrent cancer. BREVAGen<sup>TM</sup>'s addressable market starts with the 90% of people who test BRCA negative, should easily extend to the 1 million women in whom breast biopsies return indeterminate results and is ultimately applicable to all women in the US over the age of 35.

## Tests Similar to BREVAGen™

Two companies have products similar to BREVAGen<sup>™</sup>. They are deCODE Genetics of Iceland and InterGenetics based in Oklahoma USA.

deCode's test is calibrated for Europeans and they do not have a US presence Following the collapse of Lehman Brothers, deCode went into chapter 11 under the US Bankruptcy Code, but emerged in April 2010 as a private company. The deCODE BreastCancer<sup>TM</sup> test looks at 16 SNPs and is calibrated for European women. The main issue with deCode's test is that it doesn't fit in with current clinical guidelines, a situation which will slow adoption of the test and could leave the physician with conflicting information. The test can be ordered from various localities at an out-of-pocket price of USD1650. This is substantially more than the USD945 for the BREVAGen<sup>TM</sup> test. deCode currently has no US presence.

InterGenetics test looks difficult for physician's to support

InterGenetics have developed a test they call OncoVue, which is based on a panel 22 SNPs. There appears to be little, if any, published data on the test and it has not been validated. The test is also not for use "outside of the InterGenetics-qualified ordering facilities", which might be suggesting that the test results are difficult to interpret. Obviously, this would not be a positive for the test. It is also not clear that measuring any more than 7 SNPs adds any value to the test..

Other companies, such as Navigenics, offer SNP-based testing that may provide some indication of breast cancer risk. These companies appear geared toward providing basic genetic information direct to consumers, rather than through a formal medical framework. There are significant regulatory issues with providing such information direct to consumers and any competition these companies might provide to BREVAGen<sup>TM</sup> is likely to be minimal.

#### The Molecular Basis of Cancer

While the success of BREVAGen<sup>TM</sup> would likely be a company making event for GTG, becoming a major player in the area will be dependent on GTG's ability to source further proprietary tests to add to its overall product offering.

Many cancers are the result of what are termed somatic mutations. Somatic mutations are ones that occur in a cell in the body, excluding the male sperm and female's eggs. For example, the development of breast cancer starts with a single mutation in a single cell within the breast.

The mutations that ultimately give rise to cancer usually lead to a state where further mutations are likely to occur, either by reducing the cells ability to fix its DNA or by simply increasing the rate

Cancer is an ideal disease for the application of molecular diagnostics at which the cell divides. The latter leads to more cells carrying the original somatic mutation, which makes it more likely that the next mutation required to move the cell down the cancerous path will occur in a cell carrying the original mutation.

Ultimately, enough mutations occur such that the cancerous cells gain the ability to move through out the body (termed the ability to metastasise), settle in unwanted parts of the body (e.g. the lungs) and begin to affect the body's overall ability to function, ultimately causing death.

There is no single pathway down which a cell travels as it progresses from a normal to a cancerous state. Numerous genes may or may not be involved in the progression to cancer. The point being that we are probably only scratching the surface in terms of useful personalised medicine tests that can provide actionable information to physicians.

## **Breast Cancer - A Good Focus**

As previously mentioned, GTG appears to be heading toward a sub-specialism in breast cancer testing.

The success of Myriad Genetics and Genomic Health provides strong evidence of the market's appetite for better breast cancer diagnostics and validate any strategy GTG puts in place to expand further into this area

One area of particular interest in breast cancer is the use of biomarkers to define a breast cancer sufferer's prognosis and what drugs are best used to treat a particular individual's breast cancer.

Breast cancer, specifically, is a leading area for the application of molecular diagnostics Three principal biomarkers are currently used to classify breast cancer fairly routinely and help with prognostic and treatment decisions. They are the estrogen receptor, the progesterone receptor and the human epidermal growth factor receptor 2 (HER2). The combinations of these biomarkers expressed by breast cancer lead to further classification of the cancer.

For example, breast cancers that are negative for the estrogen and progesterone receptors won't benefit from treatment with hormone receptor antagonists, such as tamoxifen. Similarly, cancers that are not HER2 positive will not respond to the drug Herceptin, a monoclonal antibody that targets HER2. Breast cancers that do not express any of these biomarkers must be treated with chemotherapy.

The Oncotype DX Breast Cancer Test operates in this space and is used to determine whether or not a patient will benefit from chemotherapy in addition to targeted drugs. It is desirable to avoid chemotherapy if possible because chemotherapy is toxic to both healthy and cancerous tissues, it just happens to be more toxic to cancer cells. It is also why chemotherapy has so many side-effects.

While Oncotype DX currently plays a successful role in breast cancer management, the need for further information is still great and will only get greater as new therapeutics for breast cancer are developed. Other markers have been discovered. Some of these are at the research stage, while others are currently being commercialised. As with cancer in general, the growth opportunities for new tests in the area of breast cancer alone appear staggering.

## Possible GTG Acquisitions

The path forward for GTG to expand in the cancer diagnosis and management area appears to be straightforward. As stated earlier, events have conspired in such a way that it is cheaper to acquire tests that are at a late stage of development, or even market ready, than it is to develop them from basic research. Thus, M&A is the way forward and the direction GTG is already headed in. Obviously, eventually capital markets will come back and companies that are currently amenable to acquisition may not be so later on. This will and should provide impetus for GTG to act relatively quickly without compromising the normal process of due diligence required in such transactions.

Based on market characteristics and GTG's current offerings, acquisitions will probably be evaluated according to the following criteria:

- Utility of the company's products in cancer diagnosis and management
- Clear clinical need
- · Fit with existing US operations
- Products close to or on market
- Currently reimbursed or clear reimbursement strategy
- Price

- Size of target population
- Number/localisation of treating physicians.

Acquisitions likely first in breast cancer area, followed by other cancers Again, it seems likely that GTG will look to add to its breast cancer franchise first and then move on to other cancers. It is less obvious what these other cancers will be. There is an association between the BRCA genes and ovarian cancer and a move in this direction has some merit. The market for ovarian cancer, however, is relatively small and at this stage less amenable to personalised medicine. The colorectal cancer market is large and more amenable to personalised medicine. In fact, the first cancer gene identified was for colorectal cancer. How a move into colorectal cancer would dovetail with an existing breast cancer focus would need to be carefully considered.

## The Long-Term View

A shift to the US Likely

Should BREVAGen<sup>TM</sup> sales meet expectations and further suitable acquisitions be identified, **It** seems likely that GTG would shift operations to the US and continue to focus on that market. The obvious advantage is that turnaround testing times would be reduced. While not an immediate or probably even medium term concern, competition will ultimately increase and turnaround times are likely to become important.

In theory, shifting GTG's operations to the US would not be difficult. The economic conditions there mean that acquiring space for a laboratory is likely to be cheap. Particularly given the leverage that creating jobs would give GTG if they were to negotiate with a state or local government. GTG has also already developed a CLIA-compliant quality system which could simply be dropped into any new laboratory they set-up. Finally, GTG has approximately \$2.5 million dollars worth of laboratory equipment already on its balance sheet which could be shipped to the US and used to fit-out the new laboratory, at a much reduced cost to buying new equipment.

BREVAGen<sup>™</sup>'s likely to see historical operations sold

BREVAGen's<sup>TM</sup> success will also have implications for the Company's historical operations. At the moment, they provide revenue and a base from which to move into the US market which reduces risk. Significant revenues from BREVAGen<sup>TM</sup>, however, seem likely to leave the existing operations immaterial to GTG's revenue generating ability. In this case, they will become more valuable to local players in the pathology/testing industry and it is likely that they would be sold

An argument could be made that the historical operations are already immaterial to GTG's future. The revenues from GTG's patent estate are likely to be sufficient in conjunction with prudent capital raising efforts to fuel a shift to the US and GTG's growth strategy.

Recognising the risk inherent in launching a new product in a new market, we like the downside protection that the existing operations afford GTG at the moment. This view will probably change, however, once we begin to see the signs of significant BREVAGen<sup>TM</sup> sales.

### The Board

A strong board which will evolve with the company

GTG's board is strong in the areas of accounting financial management and the management of small technology companies, both listed and unlisted. Dependent upon the speed of success of GTG's BREVAGen<sup>TM</sup> product, we would expect to see some changes at the board level, such that the board moves in the direction the company is heading.

**Sidney Hack**, *Chairman*, CPA. Appointed to the board in November 2008, Mr Hack was a partner in the Chartered Accounting firm Hack Anderson and Thomas. He has extensive experience in the areas of auditing, financial planning and taxation. He has served on various company boards and is the Chair of GTG's Audit and Corporate Governance Committees.

**Dr Paul MacLeman,** *Chief Executive Officer*, BVSc, MBA, Grad Dip Tech Mgt, Grad Cert Eng, FAICD. See management section earlier.

**Huw Jones**, *Non-Executive Director*, BSc(Hons), MBA. Appointed to the board in November 2008, Mr Jones is currently the Chief Executive Officer of environmental services company, Aeris Environmental Ltd (ASX:AEI). Before Aeris, Mr Jones was Managing Director of Datex-Ohmeda Australasia, now part of GE healthcare. He is currently a non-executive director of Nascor Pty Ltd, an Australian–based company which develops, manufactures and markets innovative neonatal products for hospital use. Mr Jones is a member of GTG's Audit and Corporate Governance Committees.

**Dr Malcolm Brandon**, *Non-Executive Director*, BAgrSci, PhD. Dr Brandon is currently the Managing Director of Clone International, a company which uses cloning technologies to breed

cattle, sheep and horses. He was appointed to the GTG board in October 2009. He is a founding Director of the Centre for Animal Biotechnology and was also a Co-founder and Director of Stem Cell Sciences Pty Ltd and Smart Drug Systems Inc. Dr Brandon serves on GTG's Audit Committee.

**Tommaso Bonvino**, *Non-Executive Director*, FAICD. Mr Bonvino was appointed to the board in November 2009. He was a former Chief Executive Officer of once listed IM Medical (ASX: IMI). His core area of expertise is product development supported by management positions in a number of European firms with a southeast Asia focus. Mr Bonvino was a Board Member of the Italian Chamber of Commerce from 2001 to 2009, spending the last four years as Chairman. He is also a member of GTG's Corporate Governance Committee.

## **Genetic Technologies Limited - Financial Data**

Table 3. Profit & Loss

	AUD millions				
	2010A	2011F	2012F	2013F	2014F
Revenue					
Existing Operations	5.8	6.0	6.0	6.0	6.0
Licensing	4.0	15.5	9.1	19.1	23.1
BREVAĞen™	0	0	2.6	11.7	28.4
Total Revenue	9.8	21.5	17.7	36.8	57.5
cogs	2.7	2.8	3.7	6.9	12.8
Gross Profit	7.0	18.7	14.0	29.9	44.8
Expenses	16.5	17.7	10.4	14.2	17.0
Profit*	-9.4	1.0	3.5	15.7	27.8

<sup>\*</sup>Profit before and after tax are the same due to accumulated losses for the period given.

Table 4. Cashflow

			AUD millions		
	2010A	2011F	2012F	2013F	2014F
Cash Inflow	11.6	21.5	17.6	36.8	57.5
Cash Outflow	16.1	20.5	14.1	21.1	29.7
Inc/Dec Cash	-4.5	1.0	3.5	15.7	27.8
Opening Cash	7.8	3.3	4.3	7.8	23.5
Closing Cash	3.3	4.3	7.8	23.5	51.3

Table 5. Balance Sheet (unaudited as at 31 March 2011)

	AUD
Current assets	
Cash and cash equivalents	7,151,916
Trade and other receivables	677,611
Prepayments and other assets	465,490
Performance bonds and other deposits	124,139
Total current assets	8,419,156
Non-current assets	
Property, plant and equipment	966,743
Intangible assets and goodwill	1,763,149
Total non-current assets	2,729,892
Total assets	11,149,048
Current liabilities	
Trade and other payables	1,369,911
Interest-bearing liabilities	53,280
Deferred revenue	263,049
Provisions	662,921
Current liabilities	2,349,161
Non-current liabilities	
Interest-bearing liabilities	30.880
Provisions	112,795
Total non-current liabilities	143,675
Total liabilities	2,492,836
Net assets	8,656,212
	0,030,212
Equity	<b>7</b> 0 0-0 10-
Contributed equity	72,378,105
Reserves	1,622,201
Accumulated losses	(65,516,683)
Parent entity interest	8,483,623
Minority interests	172,589
Total equity	8,656,212

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#### Disclaimer

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#### **Explanation of Lodge Partners recommendation system:**

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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