Lodge Partners Research
ABN: 25 053 432 769
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BUY A$0.18

Genetic Technologies (GTG)

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BREVAGen™: Solid Characteristics

GTG Company Data

Code	ASX:GTG; NASDAQ:GENE
Price	AUD0.18
12 month price target	AUD0.57
Implied return	216%
Shares on issue	464,605,152
Market capitalisation	AUD83.6m
12 month price range	AUD0.02 – 0.35
ASX Monthly Turnover (July)	26.8m
NASDAQ Monthly Turnover*	249m

* 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*	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

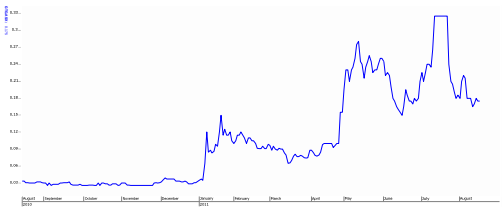
Board of Directors

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	32.5%

Share Price Chart



Genetic Technologies Limited (ASX:GTG; NASDAQ:GENE) recently completed an AUD11.7 million equity capital raise to domestic and US institutional and sophisticated investors. The money raised is earmarked for acquisitions and to accelerate the roll out of their flagship breast cancer risk test, BREVAGen™, in the US.

We expect BREVAGen™ sales to provide the main catalyst for share price appreciation over the short to medium term, and GTG's sales figures will be closely watched by the market. Importantly, GTG has other revenue streams which provide downside risk mitigation (as noted in Lodge Initiating Coverage, dated 4 July 2011).

Comparative Analysis

This note examines the prospects for BREVAGen™ sales by looking at the performance of two diagnostic companies Genomic Health, Inc. (NASDAQ Code: GHDX) and Cellestis Limited (ASX Code: CST).

We have chosen these comparables to provide investors with both a US and domestic context for GTG and BREVAGen™. We believe that US-based Genomic Health's breast cancer test Oncotype® DX Breast Cancer Assay provides the closest comparable in product terms, while Australian-based Cellestis provides a useful reference point for domestic investors with its tuberculosis test QuantiFERON®-TB.

The sales ramp of the molecular diagnostic Oncotype® DX has been extraordinarily fast. Sales have grown from USD0.2 million in its first full year of sales in 2004 to USD175 million in 2010. 2011 sales are expected to be USD208 million, representing a 19% increase on 2010. Genomic Health derives almost all of its income from Oncotype® DX and has a current market capitalisation of USD733 million.

BREVAGen™ is similar to Oncotype® DX in the following ways:

- Meets an unmet medical need (no entrenched competitor)
- Has reimbursement in place
- Is unencumbered by US Food and Drug Administration regulations
- Slots easily into current patient management
- And is focussed on a market accustomed to new diagnostics

Consequently, we believe there is a high probability of GTG continuing Australia's good run with medical devices (which include diagnostics) and GTG one day being considered in the realm of Cochlear, Cellestis, Resmed and Sirtex.

Recommendation

BREVAGen™ sales commenced in late June 2011 and we are extremely impressed with the approach taken by management in preparing for and executing its US market entry. We expect BREVAGen™ sales to grow solidly over the coming year. **We reiterate our BUY Recommendation with a 12 month price target of AUD0.57.**

Background

Downside risk mitigation

In our initiating coverage report on GTG dated July 4, 2011, we specify a value for the Company's intellectual property portfolio of AUD72 million and a value for the historical operations of AUD6.4 million. With cash reserves of approximately AUD17 million, this gives the company a value of AUD95 million, excluding BREVAGen™. This value is robust and we indicate it should provide down-side risk mitigation for investors at GTG's current share price.

BREVAGEN™ provides upside in short to medium term

Short to medium term upside in the Company, however, comes from its recently launched breast cancer risk test, BREVAGen™.

Given the significance of BREVAGen™ in GTG's future, we have undertaken an examination of two companies with previously launched products comparable to BREVAGen™ in an effort to understand factors associated with a successful diagnostic and whether these factors apply to BREVAGen™.

To put GTG and BREVAGen™ into both a US and local context, we have chosen to compare GTG to US-based company Genomic Health (NASDAQ:GHDX) and the local company Cellestis Limited (ASX:CST). Sales revenues for each comparator can be assumed to be completely derived from a single product, Oncotype® DX Breast Cancer Assay (hereon referred to as Oncotype DX) in the case of Genomic Health and QuantiFERON®-TB in the case of Cellestis.

The Genomic Health Story

Our initiating coverage note contains a significant amount of information on Genomic Health and Oncotype® Dx.

In short, the company launched its diagnostic, Oncotype® DX, in January, 2004. Genomic Health floated in September, 2005, raising USD60 million at a market capitalisation of US95.5 million. The company is currently valued at USD733 million.

Oncotype® DX measures the expression of 21 genes by the cancer of a breast cancer patient. A recurrence score calculated on the expression results indicates which of a certain type of breast cancer patient will benefit from chemotherapy. That is, the test helps the physician determine how the patient is best treated.

Oncotype® DX is what is termed a laboratory developed test. These types of tests do not require US Food and Drug Administration (FDA) approval. They must simply be performed in a Clinical Laboratory Improvement Amendments (CLIA) certified laboratory to satisfy regulators in most US states (a few states have additional requirements).

At the time of its launch, a test to determine which breast cancer patients would benefit from chemotherapy represented an unmet medical need. In 2008, Dutch company Agendia launched MammaPrint® in the US to compete with Oncotype® DX. Despite the fact that MammaPrint® carries the apparent weight of FDA approval and that it analyses the expression of three times as many genes as Oncotype® DX, it has had little success in taking market share away from it.

The Cellestis Story

Cellestis was floated in April 2001 at AUD0.25, with the capital raised by the company to be put toward developing diagnostic tests based on its QuantiFERON® technology. The float price implied a market capitalisation of AUD20.5 million. Recently, Qiagen made a successful bid of AUD362 million for the company.

The QuantiFERON® technology measures the reaction of a section of the immune system which provides cell mediated immunity. As the name implies, cell mediated immunity is a process where specialised cells attack invading organisms directly rather than through the production of molecules termed antibodies.

The biggest application of the QuantiFERON® technology is in the detection of *mycobacterium tuberculosis* (TB) infection, the causative agent of the disease tuberculosis.

Traditionally, TB infections have been detected using the Mantoux test and over many years the test has become well-entrenched in clinical practice. This test involves injecting a purified tuberculin protein derivative into the skin. In persons who have been exposed to TB, the presence of the tuberculin protein causes an immune reaction which presents itself as a raised hardened area of skin where the protein was injected.

The Mantoux test, however, has numerous problems. The first and foremost being that a person who has been vaccinated against TB will produce a positive result, as can subjects who have been exposed to non-tuberculosis mycobacteria. Further issues include that the Mantoux test requires two trips to the physician – one for injection of the test material into the skin and, a second a day later, to determine if the patient has reacted to the test material. The Mantoux test is also semi-qualitative, which, in turn, makes the test subjective and the result dependent upon the person doing the test.

Laboratory tests do not require FDA approval

Cellestis' original test for TB, named QuantiFERON®-TB, had significant advantages over the Mantoux test but still reacted with non-tuberculosis mycobacteria. In its next iteration, Cellestis incorporated reagents which made the test specific for *mycobacterium tuberculosis.* This version of the test, named QuantiFERON®-TB Gold, has a greater specificity for tuberculosis infection than its predecessor or the Mantoux test. This version of the test received FDA approval in late 2004. Like its predecessor, the Gold version of the test only requires one trip to the doctor's office and its results are not subject to the variation of interpretation seen with the Mantoux test. A final iteration of the test, termed QuantiFERON®-TB Gold In Tube, was approved by the FDA in late 2007. This version of the test gave users more flexibility in terms of how quickly the samples needed to be returned to the laboratory for analysis.

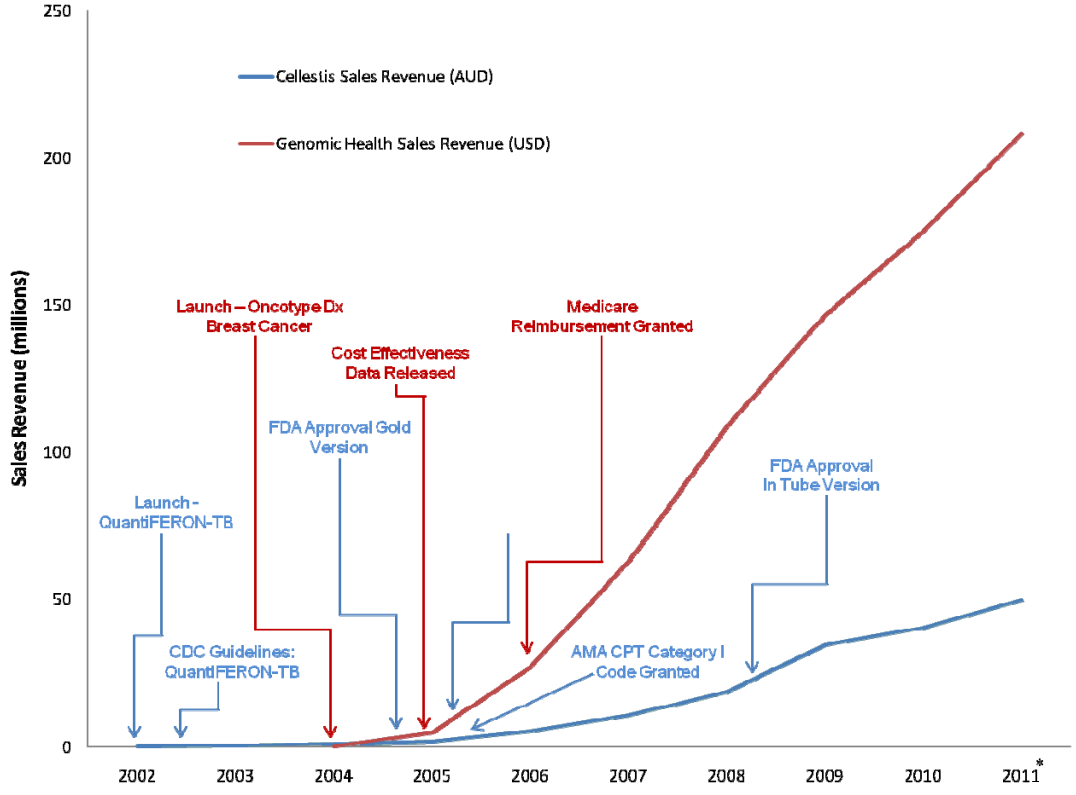
Sales Revenue Generated by Cellestis and Genomic Health

As can be seen in figure 1, based on revenue, sales of Oncotype® DX have clearly ramped up much faster than those of QuantiFERON®-TB.

Targeting an unmet medical need is a significant advantage

Uptake of Oncotype® DX was fairly strong from launch. The strong sales from launch probably reflect the fact that at the time the Oncotype® DX was satisfying an unmet medical need. There was a sizeable inflexion in sales during 2005 which may have corresponded with the release of economic data supporting the cost effectiveness of Oncotype® DX, as well as additional clinical data supporting the use of the test. The inflexion in 2006 sales can be attributed to the granting of Medicare reimbursement for Oncotype® Dx. Inclusion of Oncotype® Dx in the American Society of Clinical Oncologists and National Comprehensive Cancer Network breast cancer treatment guidelines in late 2007 and early 2008, respectively, appear to have had little impact on sales indicating physicians had accepted the utility of the test before the professional bodies.

Figure 1. Comparison of Sales Revenue of Cellestis and Genomic Health.



*2011 figures are based on analyst and company estimates.

QuantiFERON®-TB sales didn't really start until reimbursement was in place

QuantiFERON®-TB sales don't really appear to have started in earnest until the test was granted a category I Current Procedural Terminology (CPT) code and included in the US Clinical Lab Fee Schedule published by the Centers for Medicare and Medicaid Services enabling reimbursement from these bodies.

In the US, diagnostics are usually reimbursed according to CPT maintained by the American Medical Association. Emerging technologies are given temporary category III codes. While recognition of the test in a category III code is useful it is often not enough on its own to convince healthcare bodies to provide reimbursement for the test. Gaining reimbursement is made much easier when a test/product has been granted a category I CPT code. To be given a category I code a procedure must be consistent with contemporary medical practice and widely performed. Without a category I code, the company can be left to negotiate price on an individual payer basis.

This can turn into a bit of a chicken and the egg situation, where you need a category I CPT code to generate significant sales, but significant sales are required to get the widespread use required for the granting of a category I CPT code. This issue is not unique to Cellestis or QuantiFERON®-TB, any company with a highly unique technology faces it.

The launch of the "In Tube" version of QuantiFERON®-TB also appears to have enhanced sales, although exchange rate movements affecting the 2010 and estimated 2011 results appear to have obscured these increases. Unfortunately, unit sales data is not available for QuantiFERON®-TB.

Factors Accelerating Sales of Oncotype® DX Breast Cancer Assay

As stated earlier, Oncotype® DX has experienced rapid sales growth. Particular factors that appeared to play a role in this are as follows:

1] *Clear Unmet Medical Need:* Chemotherapy is an unpleasant experience. It works on the basis that it is more toxic to cancerous cells than healthy cells. The fact that it is toxic to healthy cells leads to side effects, which, in turn, makes it the unpleasant experience that it is. There are also significant costs associated with it. The benefit from chemotherapy varies from breast cancer patient to patient. A test that can determine which patients will and which won't benefit from chemotherapy will improve the quality of life of patients who won't benefit and save money through the avoidance of unnecessary treatment. Oncotype® DX fills this need for certain breast cancer patients providing the doctor with actionable information.

Reimbursement at launch possible for certain novel tests

2] *Reimbursement in Place at Time of Launch:* Category I CPT codes exist for a number of steps common between many diagnostics. For example, a category I CPT code specifies a price of USD13.00 for DNA/RNA extraction. Tests that are comprised of steps for which category I CPT codes exist can simply charge insurers using these codes, without having to specify exactly what the test is for. This makes it much easier for tests comprised of non-novel steps to generate significant revenues without having to negotiate with individual insurers or be granted Medicare reimbursement.

Women's health a proven market for molecular diagnostics

3] *Technology Ready Market:* Women's health and breast cancer, specifically, have been areas where the market has been prepared to readily adopt new technologies compared to similar technologies in other healthcare markets. Mammography-based breast cancer screening is a prime example of this. In terms of molecular diagnostics, Myriad Genetics tests for the breast cancer genes BRCA1 and BRCA2 had already alerted physicians in the area to the usefulness of molecular diagnostics and also probably contributed to accelerating the uptake of Oncotype® DX.

Factors Slowing sales of QuantiFERON®-TB

While there is no question that the QuantiFERON®-TB technology is superior to the Mantoux test from a performance point of view. Several factors appear to have worked against it in terms of its uptake by the market. A summary of these factors follows:

Mantoux test highly entrenched

1] *Entrenchment of Mantoux Testing:* The Mantoux test was created in 1907. It is a fairly simple test to perform and manufacturing of the tuberculin test material is straight forward. Consequently, given the endemic nature of TB, the Mantoux test was widely adopted by the medical community. A lack of innovation in the area has meant the Mantoux test was largely unchallenged until QuantiFERON®-TB came along. As one can imagine, when a test has been around for over 100 years, physicians become very comfortable with it and there will always be resistance to change.

2] *QuantiFERON®-TB Test Design:* As mentioned earlier, there have been three iterations of TB

tests based on the QuantiFERON® technology. Despite the fact that Cellestis entered the market in early 2002 with its first FDA approved test, it probably wasn't really *in* the market until the release of QuantiFERON®-TB Gold in late 2004 and it probably wasn't in the market with right test configuration until the approval of QuantiFERON®-TB Gold In Tube in late 2007. Given the way events transpired (availability of the new antigens, challenges in developing the "In Tube" version), it is difficult to see how management could have circumvented the need to visit the FDA three times. Nonetheless, it takes approximately a year for a diagnostic to be approved by the FDA, time during which no sales of the product occur and no market feedback is gained. Obviously, this can slow sales.

If a test is regulated by the FDA, it can be difficult to make changes based on market feedback

3] *Reimbursement:* A major factor which drives sales of diagnostics is coverage by government and private healthcare bodies. Without reimbursement, the individual or body must foot the bill themselves. While Americans are used to having to pay more for their healthcare than Australians, they are used to receiving reimbursement for, at least, part of their healthcare costs. It wasn't until the "Gold" version of QuantiFERON® was released that the test became widely enough used to qualify for a category 1 CPT code and, hence, receive clear reimbursable status.

Patients reluctant to foot the whole bill for a test

4] *Further Issues:* The initial target market for QuantiFERON®-TB comprised groups responsible for large numbers of TB tests. While getting a large group to sign up to use your product creates large revenue flows, it takes a lot longer to sign these big groups up and they often have significant negotiating strength in terms of price. While the Mantoux test is far from perfect, it has served its purpose for a long time; the medical community understands it and the infrastructure and protocols are in place for its performance. For these groups to switch to QuantiFERON®-TB, not only do they need to be satisfied that it is better than the Mantoux test, but that its benefits outweigh the risks of switching to it. Obviously, this is a much more complex question to answer.

Large powerful customers can work against a product

Relating QuantiFERON®-TB and Oncotype® DX Experiences to BREVAGen™

Like Oncotype® Dx, BREVAGen™ targets an unmet medical need and provides the physician with actionable information.

No immediate competition

BREVAGen™ faces no immediate threat of direct competition and its uptake will not be dependent on physicians switching from a well entrenched existing test that already fulfils the particular market need like QuantiFERON®-TB faced with the Mantoux test.

Actionable information that improves patient outcomes

BREVAGen™'s value-add is that it gives the patient a more accurate view of their breast cancer susceptibility. More importantly**, it gives the physician the information they need to triage women into risk categories that are associated with clear cut patient management and treatment protocols, effectively reducing the number of patients who fall into "grey" areas or inappropriate categories in which they may be over or under managed relative to their theoretical true risk of developing breast cancer.** To provide an indication of BREVAGen™'s ability to generate actionable information, its results will indicate that a physician should change the surveillance procedures and treatment for 64% percent of women at intermediate risk of breast cancer due to breast biopsy results. This translates to approximately 640,000 women per year in the US at maximal BREVAGen™ penetration. This can be compared to 25%-30% of breast cancer sufferers who will have their treatment course altered due to their Oncotype® DX result (Albain et al, Breast, 2009).

Alterations due to market feedback do not require regulatory approval

BREVAGen™, again like Oncotype® DX, is a laboratory developed test and does not require FDA approval. As a result, there is no need for GTG to seek FDA approval after they make changes to the test like Cellestis had to with QuantiFERON®-TB. Consequently, market feedback and technology advances can be incorporated into BREVAGen™ much more easily in the event that changes are required.

Reimbursement in place from launch

As an amalgamation of existing laboratory procedures, **BREVAGen™ can also take advantage of existing category I CPT codes** and, consequently, reimbursement for the test is already in place. It took four years post the first launch of QuantiFERON®-TB before it was granted a category I CPT code.

"Buy" decision straight forward

While very few physicians will simply start using a test without a period of consideration, the complexity of the decision to use the test is much more straightforward and the threshold to get them on board much lower than it is for bodies who are involved in testing a large number of individuals. Timing, budgeting, infrastructure requirements, etc really don't affect a physician's decision to suggest a patient have a test. A physician can also trial a test by recommending one of their patient's most in need have it, as opposed to the more laborious process required for a healthcare body to trial a test. This should make the decision to at least trial BREVAGen™ a

straight forward one.

Path to success demonstrated by other companies

Finally, as stated in our initiating coverage report and earlier in this report, **the breast cancer market is one that tends to adopt new technologies quickly**. With Myriad Genetics and Genomic Health having successfully introduced molecular tests to the area, products that follow in their footsteps should have an easier time traversing the terrain.

Obviously, simply being a molecular test is not enough to ensure success. Various characteristics are required and while these characteristics will vary from test to test, it is clear that BREVAGen™ shares the characteristics successful tests in the breast cancer area have. Importantly, it doesn't have various characteristics that appear to have slowed the adoption of QuantiFERON®-TB.

There are a few important aspects relevant to BREVAGen™ sales that this note has not touched that are worth mentioning.

BREVAGen fits with physician's current decision making process

The first is that BREVAGen™ test results have been designed to dovetail with existing non-competing methods of estimating breast cancer risk and current clinical guidelines. The point being that the test slots straight into the physician's usual decision making process, despite the test result influencing the final decision. The net result is that not only should BREVAGen™ fill an unmet need for the physician, but **they should also find the test easy to incorporate into their patient management decisions, further enhancing adoption**.

FDA approval, number of markers not likely to be a significant factor. First mover advantage may be great.

Secondly, The inability of MammaPrint® to take market share away from Oncotype® DX despite carrying the apparent weight of FDA approval and a larger panel of markers may well be indicating that these characteristics are not as important as one might have thought. Certainly, it seems likely that each additional marker added to a test panel will provide a diminishing return and at some point the addition of further markers will cease to substantially improve test results. The other obvious message could be that being first to market in the breast cancer testing area is very important.

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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.

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