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Bioshares

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Delivering independent investment research to investors on Australian biotech, pharma and healthcare companies.

In this edition...

What does it mean for a biotech company to turn a corner? For some it might mean re-designing equipment and surgical techniques, which is what Sunshine Heart has undertaken in the last 12 months. For Genetic Technologies a focus of cost cutting and getting its finances in order has been a huge step in the right direction. GTG is also presenting itself as a company that may deliver a new line of revenue as it seeks to sell its Brevagen breast cancer test in the US. Of note, changes at both SHC and GTG have followed the appointment of new CEOs.

Oncolytic virotherapy company Viralytics may be set for a strong run following a US$1billion deal signed between Biovex and Amgen. The deal should galvanise interest in virotherapy.

The Editors

Companies Covered: GTG, SHC, VLA

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.0%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.3%
Year 7 (May '07 - May '08)	-36%
Year 8 (May '08 - May '09)	-7.3%
Year 9 (May '09 - May '10)	49.2%
Year 10 (May '10 - Current)	31.7%
Cumulative Gain	**281%**
Av Annual Gain (9 yrs)	**18.5%**

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Extract from Bioshares –

Genetic Technologies Turns the Corner

Genetic Technologies (GTG: 12 cents, Cap $49M) has delivered an excellent quarter and first half result for this financial year. The company has announced unaudited first half revenue of over $14 million with an expected net profit after tax of $4.3 million. It's a maiden profit result for the company. It's share price has had a stunning run over this year, increasing from 3 cents at the start of this month to 12 cents.

Genetic Technologies could be split into five core businesses units, all based around the DNA analysis laboratory based in Fitzroy, Melbourne.

1. Non-coding DNA licensing revenue

Of the $14 million in revenue in the first half, $11.6 million (83%) was generated from licensing revenue from the company's broad ranging DNA patents. To date the company has generated over $65 million in licensing revenue from its patent estate.

Although one of the company's major patents expired last year, it has additional patents that take out its IP position up to 2022. Some of the licences granted are for retrospective use and also prospective use of non-coding DNA technologies. The revenue from licensing of the DNA patents remains lumpy (a $5 million licencing settlement was reached late last month), however the company is looking to bring more consistency in this revenue stream from a more systemised licensing approach towards companies that are infringing its patent estate.

The litigation work is conducted by a US law firm, with the litigation costs largely absorbed by the law firm and the proceeds divided by the law firm and GTG. The revenue from licensing should continue but is difficult to predict. The lasts 12 months has seen settlements with a number of agbio companies.

What is important about this licensing income is that it is being invested in building the company's oncology genetic susceptibility testing business. GTG's cash balance increased to $8.4 million at the end of last from $3.3 million six months earlier.

2. Paternity testing and forensics work

The company conducts paternity testing within Australia and also conducts DNA forensic test work for the NSW police force, with that contract currently due for renewal.

3. Animal genetics testing business

The company conducts DNA testing of animals, providing information such as disease susceptibility profiling, breed identification, coat colour selection and animal forensics.

4. Disease susceptibility and DNA disease testing in Australia and Asia

GTG has in-licensed genetic tests in Australia and parts of Asia to the BRCA1 and BRCA2 tests developed by Myriad Genetics. Women with either of these genetic mutations have a 60% chance of developing breast cancer during their lifetime.

– Cont'd over

GTG also provides a number of DNA and microRNA based tests in Australia and Asia, some of which have been in-licensed from other biotechs including Rosetta Genetics, TrimGen Genetic Diagnostics and Response Genetics, and other tests that are freely available to conduct. These tests include tests for genetic susceptibility to a number of diseases, detection of primary cancers from secondary cancer biopsies (cancers of unknown primaries) and tests that differentiate cancer sub-type for optimum treatment prescription.

5. US commercialisation of Brevagen diagnostic assets

The game plan for GTG is to use its DNA testing assets (facility and expertise in Fitzroy) and its DNA licensing funds, to build a US (and then rest of world) cancer molecular diagnostic business.

That business will be based around the Brevagen diagnostic test acquired from Perlagen Sciences last year. Brevagen is a breast cancer risk test that has been extensively developed by Perlegen. The test was retrospectively tested on 50,000 samples, and its accuracy prospectively confirmed in tests on around 3,500 samples from women at risk of developing breast cancer. There have been over 20 published studies assessing this test.

Around one million women each year receive an indeterminate result from a breast biopsy following a positive mammogram result. The Brevagen test can now be used to help quantify the risk of those women developing breast cancer. For women at high risk, estrogen therapy would be prescribed, to about 25% of women, which can prevent around 50% of cancers.

The test will sell for around $500, which represents an addressable market of around $500 million a year in the US. What GTG has been clever in doing is to change the DNA test from a blood-based test that needs to be conducted by pathologists, to a swab-based test that the doctor can conduct.

The swabs will be sent to Australia with DNA analysis conducted at the company's Fitzroy laboratory. GTG is waiting for its laboratory to receive US certification, which is expected by the end of March. The company will then launch the test in the US.

GTG expects to build up a sales and marketing team of 30 - 50 people over the next two years. It will invest around $2 million -$3 million a year into the business, with sales staff growing with sales. GTG is taking a predatory approach to acquire distressed assets, such as it did with the Brevagen test in the midst of the GFC for $1.5 million. (That acquisition also came with additional non-coding DNA patents.) The aim will be to add DNA-based cancer tests either through acquisition or in-licensing that its sales force can sell.

In the US the test will be reimbursed under existing codes, which the company believes will provide reimbursement for between 70%-80% of women.

In Europe the company will use distributors to sell its Brevagen tests and in other regions, including Japan, the company will look to set up partnerships.

The US operations launching Brevagen will be run by Lewis Stuart who was recently hired by the company. Stuart is a highly experienced biotech commercialisation executive. For six years he was at **CV Therapeutics**, most recently as Senior VP of Commercial Operations. He recruited and deployed over 325 cardiology specialty sales staff and launched a new first-in-class cardiology drug (Ranolazine). CV Therapeutics was acquired by **Gilead** in 2009 for US$1.5 billion. Prior to that Stuart was VP of US Sales at **Agouron Pharmaceuticals** where he recruited and deployed 105 field sales staff to launch and sell a new protease inhibitor. Agouron was acquired by **Pfizer** for US$2.1 billion.

Improvements in operations

Paul Macleman was installed as CEO of GTG in 2009. Macleman hired a new executive management team (five people). That team has driven operational efficiencies in the business. Staff count has been reduced from 80 to now 58 and tighter controls have been introduced on product costings.

Funding

The company finished last year with $8.4 million in cash. Whilst the company does not need to raise funds, there is significant interest growing in the company from US investors. Additional funds would allow more aggressive commercialisation of the Brevagen asset. It would also dilute the interest and control of the founder of the company, Mervyn Jacobsen, who instigated a spill of the board in 2008.

Summary

Genetic Technologies is certainly positioning itself in the right area, that of molecular testing, an industry that is growing in excess of 30% a year, and also in the area of personalised medicine, where therapeutics are tailored to more specific (genetic) disease profiling. It has the potential to become one of the leading molecular oncology disease susceptibility testing companies in the US however there is considerable work ahead for the company. The expansion into the US market should be monitored closely by investors.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

How Bioshares Rates Stocks

For the purpose of valuation, *Bioshares* divides biotech stocks into two categories. The first group are stocks with existing positive cash flows or close to producing positive cash flows. The second group are stocks without near term positive cash flows, history of losses, or at early stages of commercialisation. In this second group, which are essentially speculative propositions, *Bioshares* grades them according to relative risk within that group, to better reflect the very large spread of risk within those stocks. For both groups, the rating "**Take Profits**" means that investors may re-weight their holding by selling between 25%-75% of a stock.

Group A

Stocks with existing positive cash flows or close to producing positive cash flows.

Buy	CMP is 20% < Fair Value
Accumulate	CMP is 10% < Fair Value
Hold	Value = CMP
Lighten	CMP is 10% > Fair Value
Sell	CMP is 20% > Fair Value

(CMP–Current Market Price)

Group B

Stocks without near term positive cash flows, history of losses, or at early stages commercialisation.

Speculative Buy – Class A
These stocks will have more than one technology, product or investment in development, with perhaps those same technologies offering multiple opportunities. These features, coupled to the presence of alliances, partnerships and scientific advisory boards, indicate the stock is relative less risky than other biotech stocks.

Speculative Buy – Class B
These stocks may have more than one product or opportunity, and may even be close to market. However, they are likely to be lacking in several key areas. For example, their cash position is weak, or management or board may need strengthening.

Speculative Buy – Class C
These stocks generally have one product in development and lack many external validation features.

Speculative Hold – Class A or B or C

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