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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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Bioshares

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

Biotech IPO Window: "Open"

In the last two months, two biotech companies have successfully listed on the ASX, **Reva Medical** and **Bioniche**. Both companies are trading above their issue price with a third company, **Bluchiip**, due to list in March and more to come. The IPO window has certainly opened in Australia following massive Australian biotech deals last year and an improved stability in global financial markets.

What is interesting is that the two companies that have listed are both based in North America. Reva Medical is based in San Diego and Bioniche is based in Canada. The continuing success and building interest in the sector locally are perhaps two of the reasons for international companies listing on the ASX. Heartware International, which is based in the US and listed locally, is one company that has enjoyed very strong market support and is now capitalised in excess of $1 billion with its share price doubling in 2010.
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Reva Medical

Reva Medical is developing a biodegradable coronary stent. It listed at a share price of $1.10, raising $85 million. Its pre-money capitalisation was $275 million. The company's share price has increased 17% since listing giving it a market capitalisation of $422 million.

Bioniche

Bioniche, which is also listed on the Toronto Stock Exchange (in 1992), listed last week on the ASX at $1.45, raising $12.5 million. It finished the week at a $1.50, a 5 cent premium to its listing price. Last month Bioniche also raised C$16.7 million in Canada. Bioniche has an animal health business that sells 60 animal health products such as vaccines. In 2010 that business generated sales of C$27 million.

Bioniche is managing a human health drug development program. Its lead program is in Phase III trials for the treatment of bladder cancer. That program uses a mycobacterium to stimulate the immune system. In 2009, the company signed a deal with **Endo Pharmaceuticals** to commercialise the technology, which involved a $20 million upfront payment with a total deal value of $110 million.

Bluechiip

Bluechiip has filed a prospectus with the ASX and is seeking to list in March (closing date 28 February) to raise at least $3 million and up to $6 million. The company has

– Cont'd on page 4

Recent ASX Biotech IPOs

Company	Headquarters	Listing date	Funds raised/ to be raised	IPO Price	Current price	Change
Reva Medical	San Diego	Dec 2010	$85M	$1.10	$1.29	17%
Bioniche	Ontario, Canada	Jan 2011	$12.50	$1.45	$1.50	3%
Bluechiip	Melbourne	Mar 2011	$3-$6M	$0.25	-	-

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.

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.

– Cont'd over

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

Sunshine Heart Update

Sunshine Heart (SHC: 3.4 cents) has set several important objectives for 2011, including commencing a pivotal trial of its C-Pulse heart assist device, gaining CE mark approval, thus allowing sales to commence in Europe, and initiating a Nasdaq listing to raise funds to support the pivotal trial. In the order of US$40 million will be needed to fund the trial. However, it should be noted that the C-Pulse device is reimbursed in the US at a rate of $54,000 per procedure.

The pivotal trial will most likely enroll 260 patients randomized to receive the implanted device or standard of care medical therapy. Sunshine Heart has noted that another company developing a comparable technology negotiated endpoints with the FDA which included quality of life, the number of patients alive after 12 months of implantation and rates of re-hospitalisation, the implication being that these endpoints could also be adopted by Sunshine Heart.

The device is being positioned as a treatment to relieve the symptoms of heart failure and halts disease progression, for those patients categorised as Class III/IV ambulatory heart failure patients

Sunshine Heart did not meet its 2010 objective of completing enrolment of all twenty patients in its feasibility study (as of December 31, 18 had been implanted). Three patients had been ready to be implanted in December, however, discrepancies were found between measurements of patients (e.g. treadmill recordings, CT scans, six minute walk) made at the clinical site and when checked again at an independent laboratory.

Despite these issues, the company remains close to completing the feasibility trial, and it should be noted that 8 out of 18 patients were enrolled in 2010 within six months of each other. The company's rate of progress under new CEO Dave Rosa is a promising sign for a company that had been slow to deliver in earlier years.

A key advance for the company during 2010 was to change the surgical technique for implanting the device from a full sternotomy to a minimally invasive approach that is very similar to the minimal invasive approach used for aortic valve replacement.

More changes are being planned for the device, including the development of a smaller single system driver and battery unit.

The company is also aiming to test and develop a fully implantable device within 18 months. A challenge with a fully implantable device is that an electrical current must cross the skin to a pad inserted within a layer of skin tissue. However, the company believes that issues around the effects of electrical current crossing the skin may be much less compared to VAD devices with transcutaneous power systems which require much more electrical power.

With a fully implantable device the design of the cuff will also change. (The cuff is the component that wraps around the aorta and which is inflated and deflated, compressing and decompressing the aorta to improve blood flow.) A reservoir of fluid will be used to provide the dynamic force for counter-pulsative pressure.

A fully implantable device is the real end-game for Sunshine Heart, or for that matter a much larger firm that may acquire it if results from the feasibility study are convincing. A fully implantable device (implanted using a minimally invasive technique) opens up the device as a potential treatment for patients who do not respond to pacemakers. This is in addition to being used to treat Class III/IV heart failure patients.

Our view is that Sunshine Heart remains is an attractive stock at current prices.

– Cont'd over

Viralytics – Interest in Oncolytic Virus Therapy Heats Up

The last few years has seen a clear embracing of emerging technologies by pharmaceutical companies in addition to the traditional small molecule drug development and protein drug therapies.

The drug class termed biologics has been well and truly adopted and successfully commercialized in antibody drugs for over 20 years. Drug development using RNAi technology has been taken on board in the last five years. In 2006 **Merck** acquired **Sirna Therapeutics** for $1.1 billion. The following year **Roche** paid **Alnylam** $331 million up front in a $1 billion total deal value to get access to that company's technology. (Locally, **Benitec** holds one of the four key global patents in the RNAi field.)

Last year saw the first cancer vaccine finally approved by the FDA. **Dendreon**'s autologous cancer vaccine Provenge was approved in April 2010 and Dendreon is now capitalised at $5 billion.

In December **Mesoblast** announced one of the largest ever biotech deals with **Cephalon** for rights to some of the applications of its stem cell technology. The deal included an upfront investment of $350 million with a total potential deal value of $2.05 billion.

Last week it was the turn of oncolytic vaccines, that is the use of viruses to fight tumours. The leading company in this space is **Biovex Group**, which is a private US biotech. It signed a deal last week with **Amgen** which included a $425 million upfront payment and a total deal value of $1 billion. The relevance of this deal for Australian investors is for Viralytics (VLA: 3.4 cents, Cap $19M) which also has an oncolytic cancer vaccine program.

In *Bioshares* 363 (see attached) we covered Biovex technology in a report on Viralytics. The interest in Biovex is due to stunning Phase II trial data in 50 patients with inoperable Stage IIIc/IV melanomas. The treatment was able to deliver a complete clinical response in 20% of patients (10), a partial response (more than 30% reduction in disease burden) in a further four patients, and stable disease in a further 10 patients. Remarkably, the treatment also shrunk distant tumours.

Biovex uses a gene deleted herpes virus. Viralytics is using the *Coxsackievirus*. One advantage for Viralytics is that only 25% of the population have been exposed to this virus, compared to 85%-90% with the herpes virus. Previous exposure means there may be circulating antibodies to the virus that may reduce that treatment's effect. With oncolytic virotherapy, there is only a two week treatment window where the patients remain immuno-naïve to the virus. The ability of viruses to attack cancer cells is potentially responsible for some patients' unexplained complete recoveries from cancer disease.

While Biovex is enrolling patients into a Phase III study, Viralytics is looking to initiate a Phase II study in the US. The company submitted an IND with the FDA in November last year. Last month the FDA informed the company that it had a number of questions that needed to be addressed before the trial could proceed.

It's not surprising that the FDA is very cautious in allowing a new trial to proceed using a novel approach such as oncoloytic virotherapy. Going in the company's favour is that Biovex (and another company **Oncolytics Biotech**) is helping to pave the way for this novel medical technology. To date over 1,000 patients have been treated with oncoloytic virotherapies.

Viralytics believes it can comfortably address the questions raised with the FDA, which once it does the FDA will have 30 days to respond.

Viralytics finished the year with $5.2 million (including a tax rebate received at the start of January) and it has a further $1.5 million of funding through its convertible note. It has a burn rate of around $4 million a year although that may increase once the Phase II trial begins.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

– IPOs from page 1

developed a wireless tracking technology that will compete with barcoding and RFID. Initial applications will be targeted to medical storage area such as storage of stem cells. (An IPO preview will be provided in the next edition of *Bioshares*.)

Other companies

Other biotechs with an IPO in the planning include **Relevare Pharmaceuticals**, which is based in the US but was previously known as the Melbourne-based biotech CNSBio.

Bioshares

– Sunshine Heart continued

Sunshine Heart is capitalised at $34 million and retained cash of $12 million at December 31, 2010.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

Bioshares Model Portfolio (28 January 2011)

Company	Price (current)	Price added to portfolio	Date added
Somnomed	$0.95	$0.94	January 2011
Phylogica	$0.078	$0.053	September 2010
Sunshine Heart	$0.034	$0.036	June 2010
Biota Holdings	$1.30	$1.09	May 2010
Tissue Therapies	$0.64	$0.21	January 2010
QRxPharma	$1.40	$0.25	December 2008
Hexima	$0.34	$0.60	October 2008
Atcor Medical	$0.10	$0.10	October 2008
Impedimed	$0.79	$0.70	August 2008
Patrys	$0.10	$0.50	December 2007
Bionomics	$0.38	$0.42	December 2007
Cogstate	$0.24	$0.13	November 2007
Sirtex Medical	$5.80	$3.90	October 2007
Clinuvel Pharmaceuticals	$2.21	$6.60	September 2007
Starpharma Holdings	$0.87	$0.37	August 2007
Pharmaxis	$2.75	$3.15	August 2007
Universal Biosensors	$1.52	$1.23	June 2007
Acrux	$3.61	$0.83	November 2004
Alchemia	$0.70	$0.67	May 2004

Portfolio Changes – 28 January 2011

IN:
No changes

OUT:
No changes

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

Sell

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