ISSN 1443-850X

In this edition...
Biotech companies have a habit of morphing, changing, growing and evolving. No better an example of this is Melbourne-based Genetic Technologies, a company we expect to undergo a period of evolution under the management of its recently installed CEO Michael Ohanessian. The company has had a chequered past but may be on the cusp of a bright future.

Elsewhere we update readers on an interesting technology access deal Arana Therapeutics signed with this week with German company Greenovation and also include our latest 'Five Stock' snapshot.

The editors
Companies covered: AAH, ACG, GTG, IMU, NAN, PBT, SHC

	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 - current)	-5%
Cumulative Gain	**98%**
Av Annual Gain (7 yrs)	**17.8%**

Bioshares is published by Blake Industry & Market Analysis Pty Ltd.

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Individual Subscriptions (48 issues/year)
$320 (Inc.GST)
Edition Number 266 (6 June 2008)
ISSN 1443-850X

Bioshares

6 June 2008
Edition 266

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

The Evolution of Genetic Technologies

Genetic Technologies (GTG: 10.5 cents) is a biotech company that has recently moved into a cash flow positive position and is now working on the next phase of its corporate evolution. In the first nine months of this financial year the company generated a net positive cash flow of $2.3 million on the back of $12.1 million sales (as measured by receipts from customers). The company has had somewhat of a volatile past, reaching a capitalization of $2.5 billion in 2001, to be now capitalised at $38 million.

Last year some of the company's executives were being investigated by ASIC in relation to trading in the company's securities and the then CEO, Dr Mervyn Jacobson, announced plans to step down following selection of a new CEO. In September last year a new CEO, Michael Ohanessian, was appointed. With a new CEO at the helm, the company is looking to transform its business beyond the existing reliance on its gene patent licensing revenue, which begins to expire in 2010.

It was long thought that the non-coding DNA sections, or junk DNA, had no relevance in the development of therapeutics or diagnostic markers. In the late 1980s Dr Mervyn Jacobson and Dr Malcolm Simons formed **Gene Type A.G.** around these non-coding DNA patents. In 2000 the company listed on the ASX as Genetic Technologies. Since 2001 these patents have generated over $38 million in licensing and royalty income, with $11.3 million received in FY2007, bringing the total revenue for that year to $15.3 million.

It has been a long and sometimes bitter pursuit for the company, requiring constant litigation, or threat of litigation to any biotech companies using non-coding DNA technology without license, starting with the largest infringing biotechs. Over the last seven years, the company has negotiated at least 36 commercial licensing contracts and six research licenses.

Expiry of patents

Moving forward, the company's business needs to evolve past the expiry of its core non-coding patents. The company has two core patents: the Intron Sequence Analysis (ISA) patent, which expires in the USA in 2010, and the Genomic Mapping patent which expires in the US in 2015.

The 'ISA' 2010 patent

The first patent expiring in 2010 in the USA is more valuable as it is easier to prove infringement. Infringement of this patent can be prosecuted as long as the action begins prior to patent expiry and damages can be claimed for the prior six years. It applies to all genes across all species. The second patent expiring in 2015 covers 'regions' of the genome.

Cont'd over

Genetic Tech. cont'd

There exists a need for Genetic Technologies to initiate action against as many infringing companies as is possible prior to 2010 for the ISA patent. The company uses third party licensing contractors to pursue groups infringing its patents and is looking at ways to accelerate this process prior to 2010. The company stated last year that it was engaged in negotiation with 39 parties, of which a few have now settled.

Life after patent expiries: The GTG of the future

The plan for Genetic Technologies is to focus on expanding its genetic testing business. In FY2007, the company generated revenue of $3.1 million from its genetic testing, up 22% on the previous year, and this is expected to approach $5 million a year following winning a three-year contract with the NSW Police Force to conduct the Forces's DNA testing.

Outcomes of patent infringement disputes over the company's non-coding DNA patents often came with payments in kind, such as equipment hardware and also rights to DNA markers. These access licenses will be used by Genetic Technologies in providing genetic testing for a range of proprietary and non-proprietary DNA markers.

DNA animal testing

In May 2003, Genetic Technologies acquired an animal DNA testing business, Genetic Science Services, which provides progeny and disease testing of a range of animals. Through its DNA cross-licensing agreement with Optigen, Genetic Technologies gained access to genetic dog profiling DNA tests. It now offers 24 different canine disease tests for 50 different dog breeds.

Disease susceptibility and personalized medicine

Disease susceptibility testing using DNA markers, such as mutations in the genes BRC1 and BRC2 for breast cancer, is already in use. In Australia there are nine government laboratories conducting the test in addittion to the public-listed Genetic Technologies. It is a point of contention for the company with government funded labs taking 12 months to complete the test versus two to six weeks for Genetic Technologies. The test is complicated with over 1000 possible point mutations in the BRC1/2 genes, costing $2000 for the full test. Through a settlement with **Myriad Genetics**, Genetic Technologies gained access to the test in 2002. Arguably it is difficult to build commercial economies of scale for such a test when competing with government funded testing centers.

Moving forward, personalized medicine - in which drugs are tailored for individuals - can be expected to accelerate DNA testing to predict drug response. An article in last month's edition of *Nature Biotechnology* suggested that genomics testing is increasingly coming into use in combination with pharmaceuticals.

In May last year **Amgen**'s drug Vectibix for colon cancer was rejected by European regulators. But this decision was overturned in December with the drug found to be effective when patients with a particular genetic mutation (KRAS mutation) were screened out. Doctors can now screen patients for that mutation using a test developed by **DxS** called the TheraScreen KRAS test.

A local example is the cancer drug Quinamed being developed by **Chemgenex Pharmaceuticals**. This drug initially failed in clinical trials because of side effects in a subset of patients. However, by screening the patients for a NAT2 genotype, the variation across patients in how quickly the drug is metabolized can be predicted and dosage selected accordingly. Patients who are slow acetylators can safety receive higher doses of the drug. Quinamed is currently Phase II trials for breast, ovarian and prostate cancer treatment.

Paternity testing

The company provides human paternity testing, for which it is the leading provider in Australia ($825 for a legally enforceable test and $520 for a non-enforceable test). An Australian paternity testing business was acquired by Genetic Technologies in 2001, called **DNA-ID** labs.

Sports gene testing

Another service the company provides is the Sports Gene Test, which can help predict the suitability of a person for sprint or endurance sports. And into the future there is the opportunity for the company to explore the possibility of providing lifestyle type genetic testing.

Other research projects

The company is pursuing a number of R&D programs. An interesting observation has been made that the immune system is cyclic and that treating patients cancer patients with chemotherapy drugs at the appropriate point of this immune system cycle could enhance the effect of drug treatment. This would allow both the immune system and the drug treatment to work in a synchronized manner to combat the disease. The program has been undergoing clinical trials in the US at a major teaching hospital. The inventor behind this technology is part-time biotech analyst, Martin Ashdown.

The company has also developed a method of separating foetal cells from the pregnant mother to test for genetic-based disorders such as Downs Syndrome in a less invasive process. The technology is called RareCellect. The company has successfully completed a trial in 150 women in two Melbourne hospitals. It is continuing development on the program.

New CEO

Genetic Technologies has made a very suitable appointment to the position of CEO. Michael Ohanessian was previously CEO of **Vision Biosystems** for seven years, a subsidiary business of **Vision Systems** which was sold to **Danaher Corporation** in 2006 for $791 million. As CEO of Vision Biosystems, Ohanessian led the transformation of that business from a pathology original equipment manufacturer (OEM) (for **Leica** and **Abbott Laboratories**) to a more fully integrated business. In 2002 Vision Biosystems acquired a pathology reagents business, **Novacastra**, for $94 million and then in 2006 bought another reagents business, **Immunovision Technology**, for $66 million. The idea was to tie reagent sale and use to its pathology equipment hardware and the strategy worked perfectly, resulting in a three-way bidding war for **Vision Systems** later in 2006.

Cont'd over

Genetic Tech. cont'd

Strategy for Genetic Technologies

The plan for Genetic Technologies is to lead a global consolidation of the emerging field of genetic testing. According to Ohanessian, there are plenty of small genetic testing businesses around the world that could be potential acquisition targets. Genetic testing lends itself to economies of scale, with the ability to deliver processing efficiencies that can be achieved in central larger laboratories, with DNA samples straightforward to transport. An example of this is the DNA forensic work being conducted for the **NSW Police Force** in Melbourne.

With a healthy bank balance, the ability to issue scrip and an aggressive management team, Genetic Technologies is in a position to become a prime mover in building critical global mass in the genetic testing services business, at a time when genetic testing is still in its commercial infancy.

Risks and other changes

One of the risks with this company remains the concentration of ownership, with the two non-executive directors Dr Mervyn Jacobson and Fred Bart owning 66% of the company. Other risks include the implementation of the company's growth strategy, and the need to grow the genetics testing business before the licensing revenue ceases. The company should continue to receive royalty streams of around $2 million up to 2015. The company is well funded with $15.3 million in cash at the end of March this year.

Summary

Genetic Technologies will require a strategic change in its business to see it past the expiry of its non-coding DNA patents. It is well placed to build a global DNA testing group, building on its existing business. The appointment of an experienced CEO with a successful track record in implementing such strategic changes, which are not without risks and challenges, will clearly benefit the company.

Bioshares recommendation: **Speculative Buy Class B**

Update – Arana Therapeutics

Arana Therapeutics (AAH: $1.05) has formed a development collaboration with a private German antibody company, **Greenovation**, to develop a number of anticancer antibody drugs. The two companies will combine their respective technologies - Synhumanisation and EvoGene from Arana and Bryotechnology from Greenovation - to jointly develop and commercialise antibody drug candidates for up to five targets.

The agreement does not specify the source of the antibody drug candidates or the targets. Greenovation is a glycoengineering company. Its core technology is the modification of therapeutic proteins (including antibodies) through the manipulation of sugar structures on proteins which can enhance their therapeutic effect.

Greenovation uses genetically modified mosses (*Physcomitrella patens*) to grow therapeutic proteins. Moss is generating interest as a protein expression system. This is because its genome can be easily manipulated and also is easy to grow, requiring only light and saltwater. This system, which is similar to the Potelligent technology accessed recently, also allows the knockout of fucose from the antibody surface leading to stronger activation of the immune system for cancer treatment.

Arana's approach has been to access the most appropriate and complete range of protein engineering technologies to apply in the development of therapeutic antibodies. To date the company has developed its own Synhumanisation technology, has accessed the Superhumanisation and EvoGene technologies through the acquisition of Evogenix, has access to a further two single domain antibody candidates through its agreement with **Domantis** (**GlaxoSmithKline**) and has accessed the Potelligent technology from **Kyowa Hakko** that reduces the level of sugars attached to antibodies (fucose).

At the end of the half-year ending March 31, 2008, Arana held cash assets of $182 million.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares Five Stock Wrap

Company	Imugene	**Code**	IMU	**CMP**	$0.08	**Cap'n ($M)**	$12.1	**Cash ($M)**	$1.74	**SI**	**1.1**
• IMU develops vaccines for the production animal industries (eg pigs and chickens) • Partner **Abic Biol. Labs.Teva** has completed a trial of six candiate vaccines for preventing coccidiosis (a parasite) infection • Abic markets an injected vaccine. Partnered vaccine uses Abic antigens and IMU FAV construct. Vaccine can be delivered orally (in water) • Next step is optimisation of selected vaccine candidate • Cocciocidiosis is currently managed with quinoline-based treatments. Partnered vaccine offers benefit of prevention and superior delivery.											
• IMU recently cleared ANZ/Opes Prime overhang • IMU's seven programs offer sufficient diversity to compensate for individual program failure											
Comment: Imugene continues to make solid progress, with programs managed cost-effectively											
Bioshares recommendation: **Speculative Buy Class B**						Timing Considerations - None					

Company	Nanosonics	**Code**	NAN	**CMP**	$0.21	**Cap'n ($M)**	$40.0	**Cash ($M)**	$26.28	**SI**	**3.9**
• NAN has developed a disinfection technology with multiple commercial applications • Technology disperses nano-particles of hydrogen peroxide into containment chamber • Lead product is a disinfector for Ulstrasound Probes • Company suffered setback with departure of CEO in Dec 07. New CEO David Radford appointed June 4. • NAN received CE mark for Ulstrasound Probes disinfection device in late April											
• Milestones:2008 H2 Lodge FDA submission • 2008 Q4 Product launch; 2009 Q1 manufacturing scale-up											
Comment: NAN is trading at attractive levels, with technology value of $14 M and EU marketing clearance received.											
Bioshares recommendation: **Speculative Buy Class B**						Timing Considerations - None					

Company	Prana Biotech	**Code**	PBT	**CMP**	$0.40	**Cap'n ($M)**	$80.6	**Cash ($M)***	$13.0	**SI***	**1.1**
• Prana is developing a drug PBT-2, a metal attentuating compound, to treat Alzheimers disease. • PBT-2 has released positive results of Phase II trial with statistically significant dose-related effect in Abeta-42 levels • Prana is now extending drug development focus into Parkinson's disease - lead candidates selected • Company is looking to partner PBT-2. We expect modest terms as Phase III study/s will require 1000's of pts and protocol challenges • Issue - substantial options/warrants (~61.4m) remain outstanding with PBT; fully diluted cap'n is $105 million											
• Milestone - Look for partnering event to reinforce share price											
Comment: PBT can be commended for raising funds to ensure viability of company and programs											
Bioshares recommendation: **Speculative Buy Class B**						Timing Considerations - None					

Company	Atcor Medical	**Code**	ACG	**CMP**	$0.10	**Cap'n ($M)**	$10.0	**Cash ($M)**	$3.7	**SI**	**0.9**
• ACG markets the Sphygmocor system which measures central blood pressure in contrast to the traditional 'cuff' measurement • Company announced USD$1.5 M contracts for clinical contract services - a repeat sale • Now more than 200 publications discuss benefits of central blood pressure management with Sphygomocor technology • Installed base now 1400 units, mostly in pharma research settings. L/T goal is to expand into the specialists and GPs market • Gross margins on systems ~ 80% • A significant challenge is to develop and optimise intermediate and long term reimbursement strategy for US market • Cash position does not include $1.9 M owed by directors											
• Milestones: 2008 H2 - FDA clearance for next generation technology											
Comment: ACG has potential to build a solid position in the pharma research market, but l/t blue sky is in the primary care market											
Bioshares recommendation: **Speculative Buy Class B**						Timing Considerations - None					

Company	Sunshine Heart	**Code**	SHC	**CMP**	$0.07	**Cap'n ($M)**	$20.4	**Cash ($M)**	$6.6	**S.I**	**0.7**
• Sunshine is developing the C-Pulse heart assist device targeted at Stage III heart failure patients • Unlike LVADs the device does not come in contact with blood and can be switched-off with-out negative consequences • Product has been implanted in five patients in ANZ trial • Company filed IDE application with FDA in June 07. Trial size 20 pts. • Six sites are ready to commence US feasability trials but FDA has demanded more information from SHC • SHC is conducting non-renounceable rights $5.4 M issue, u/w by GBS Venture partners and CM Capital											
• Milestone: FDA greenlight for US feasability trial											
Comment: Pending FDA approval of clinical trial and *rate* of trial progress, funding may still be an ongoing issue											
Bioshares recommendation: **Speculative Hold Class C**						Timing Considerations - Wait for FDA greenlight					

Notes: SI - Survival Index - refer to Bioshares 261 for explanations

** - includes recent funding*

Bioshares

Thredbo Biotech Summit

July 25-26, 2008
Thredbo Village, NSW, AUSTRALIA
www.bioshares.com.au/thredbo2008.htm

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arana therapeutics

Key Note Speaker
Dr Lester Crawford
Former FDA Commissioner

Dr Crawford's visit is supported by QRxPharma & Arana Therapeutics

QRx Pharma

Dr Crawford is an authorative and knowledgeable figure on US healthcare regulatory issues. Don't miss the chance to have a fire-side chat with Dr Crawford. Opportunities for Australian biotech companies to meet and mix with such experienced figures on Australian soil are rare and not to be missed.

Bioshares Model Portfolio (6 June 2008)

Company	Price (current)	Price added to portfolio	Date added
Cellestis	$2.89	$2.27	April 2008
IDT	$2.11	$1.90	March 2008
Circadian Technologies	$0.94	$1.03	February 2008
Patrys	$0.29	$0.50	December 2007
NeuroDiscovery	$0.10	$0.16	December 2007
Bionomics	$0.37	$0.42	December 2007
Cogstate	$0.12	$0.13	November 2007
Sirtex Medical	$3.80	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.36	$0.66	September 2007
Starpharma Holdings	$0.33	$0.37	August 2007
Pharmaxis	$1.69	$3.15	August 2007
Universal Biosensors	$0.80	$1.23	June 2007
Biota Holdings	$0.95	$1.55	March 2007
Probiotec	$1.24	$1.12	February 2007
Peplin Inc	$0.40	$0.83	January 2007
Arana Therapeutics	$1.07	$1.31	October 2006
Chemgenex Pharma.	$0.93	$0.38	June 2006
Cytopia	$0.28	$0.46	June 2005
Optiscan Imaging	$0.23	$0.35	March 2005
Acrux	$0.98	$0.83	November 2004
Alchemia	$0.41	$0.67	May 2004

Portfolio Changes – 6 June 2008

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.

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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