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In this edition...
Cellestis is a company to watch as its Quantiferon test for latent TB moves steadily towards the centre ground in TB testing.The company recently sponsored a conference on the use of interferon-gamma release assays (IGRA) , which covers Cellestis' Quantiferon tests and the T-SPOT test. Speakers discusssed the cost effectiveness of the Cellestis test, national guidelines for the use of IGRAs, and the benefit and performance of IGRAs. At present, 16 countries around the world have at least one guideline in place for using IGRAs, such as the Cellestis test.
We also feature an analysis of change of business and listing status by ASX listed biotechs over the last nine years. The rate of change has doubled in the last three years, compared to the years 2002 to 2006.
The Editors
Companies Covered: CST, Change of Business Analysis

	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 - Current)	10.3%
Cumulative Gain	**114%**
Av Annual Gain (8 yrs)	**14.7%**

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

Quantiferon Foundation Now Well Secured For Cellestis

The focus of this edition is on Cellestis (CST: $3.04), and more specifically, the wealth of information on that company's latent tuberculosis test that was recently made available to both the share market and healthcare market. At the beginning of this month, Cellestis sponsored a symposium in Dubrovnik, Croatia, on the use of interferon gamma release assays (IGRA) for detection of latent TB. There are currently two such commercial tests in place: the Cellestis Quantiferon tests, and the T-SPOT test. Below is a summary of key outcomes from that conference (the presentations are also available on the Cellestis website), and updated coverage on this stock.

Terms: IGRA (Interferon Gamma Release Assay), which covers the Cellestis Quantiferon tests and the T-SPOT test.

Cost Effectiveness Study of the Quantiferon Test

One of the key questions to be answered at this event came from a cost effectiveness study of implementing IGRA tests. Results of such a study independently conducted by Dr Masae Kawamura, the Director of TB Control at the **San Francisco Department of Health**, were presented.

Dr Kawamura highlighted some of the hurdles that need to be overcome when health bodies switch from the inaccurate 100 year old TB skin test to the blood-based IGRA tests. The issues to be considered by users include: the shift of costs from the clinic to the laboratory, which requires an initial investment; are public health bodies willing to make this cost shift; should health practitioners continue to put up with the "waste of inaccuracy of the skin test when testing our highest risk populations?" Is TB control worth it to our society and what are our moral obligations? And how can IGRA funding be sustained after the initial investment?

In San Francisco, the Cellestis Quantiferon IGRA tests are now the standard of care in testing homeless people for latent TB and foreign-born patients in San Francisco Community clinics. The Department uses around 10,000 tests a year, with total costs of US$302,000 a year (US$200,000 for purchase of the test kits from Cellestis). Reimbursement for the test is available through either state reimbursement (US$69 per test), Federal reimbursement (US$86) or private reimbursement (US$70).

Cont'd over

Dr Kawamura calculated that the estimated annual cost savings in switching from the skin-based test to the Quantiferon IGRA were between US$328,000 - US$460,000. The cost savings come from an estimated 2000 unneeded medical evaluations that are currently conducted due to false positives results from the skin test (where the Quantiferon IGRA test reduces the positive rate by an estimated 65%), and savings from unnecessary treatments of latent TB. The Quantiferon Gold In Tube test is the least costly compared to the Quantiferon Gold and the T-SPOT test, according to Dr Kawamura.

The conclusions from Dr Kawamura provide the clearest and strongest argument seen to date supporting the widespread adoption of the Cellestis Quantiferron IGRA test. In San Francisco, the Quantiferon IGRA test pays for itself and is a likely cost saving. The 24% government reimbursement rate covers the costs of the kits bought from Cellestis. The referral rate to TB clinics from this at-risk group has dropped significantly since the San Francisco Health Department switched from the skin test to the Quantiferron IGRA test. And society benefits from the convenience and the accuracy of this test.

Guidelines for Use of IGRAs

Dr Madhukar Pai from **McGill University** in Canada provided an exceptionally helpful summary on the current global guidelines in place for IGRAs. Currently 16 countries around the world have at least one guideline in place for using the IGRAs. These are: USA, Canada, Japan, France, Germany, Switzerland, Australia, Netherlands, Denmark, Czech Republic, Slovak Republic, Korea and Norway. This has been put in place in the last five years.

Some countries, such as Singapore and Finland have no guidelines in place but are using the test, and countries including Finland, Saudi Arabia and Portugal are in the process of forming guidelines for the Cellestis test. Of the 16 countries in place, 12 were not written in English, and over 50 experts in 25 countries were consulted to establish the current global guideline status. This gives readers some idea of the transforming global practice underway in healthcare to implementing IGRA tests, and predominantly the Quantiferon tests.

The guidelines are all grouped into three categories. The first is where the IGRA test must replace the skin test. The second is where either test can be used. And the third is where the IGRA test follows the skin test in a two step approach.

In Germany, Switzerland and Denmark, people going on anti-TNF alpha medication (Enbrel, Remicade or Humira) are required to be tested for latent TB using the Cellestis test. This is because the modulation of the immune system with these drugs has increased the risk of active TB infection from a latent state. And in Japan, the IGRA test is preferred for all people tested above the age of five because of the BCC vaccination which conflicts with the TB skin test.

In the USA and France either test may be used. In Australia either test may be used for refugees. In 11 countries with regulations (including Australia) it is recommended that a positive skin test

Cont'd over

result is followed up with an IGRA test. Most countries with guidelines recommend use of the test in one of the three categories prior to anti-TNF alpha therapy.

From the WHO

Dr Christian Lienhardt from the **World Health Organisation** gave a summary of the status and future of IGRA tests. There are now two IGRA tests commercially available now; the Cellestis Quantiferon tests, and the **Oxford Immunotec** T-SPOT TB test (which gained FDA approval in August 2008).

Lienhardt indicted that the skin test for latent TB has only limited effectiveness because of cross reactions with environmental bacteria and BCC vaccination. The skin test also has reduced sensitivity in people who are HIV positive. The IGRA tests are not affected by these factors because they measure the release of interferon gamma by blood T-cells produced in response to TB specific antigens. As a result these tests are highly specific immuno-diagnostic tests.

Lienhardt acknowledged this is an extremely rapidly evolving field with the WHO expecting to issue policy guidance on latent TB testing procedures in 2010.

(Readers note: The T-SPOT test is an extremely complicate test to perform requiring 10-15 laboratory steps, including two centrifuge separation steps, multiple decanting steps, adding of cell culture reagents and antigens and examination under a microscope. This procedure takes three hours to conduct, with one technician able to process around 40 samples per day. In contrast, the Quantiferon In-Tube test requires only a blood sample to be taken, placed into the tube and incubated, then analysed as a standard ELISA test. The T-SPOT test has not achieved significant commercial adoption because of the complexity in conducting the test).

Predictive Level of IGRAs

Dr Ronald Diel, from the **German Central Committee against Tuberculosis**, looked at how accurate the IGRA tests were in predicting whether infected people with latent TB would progress to active TB.

Quantiferon Hamburg Study

The study looked at 601 people who had close exposure (greater than 40 hours) to people with active TB. Of these people, 66 were Quantiferon positive, where 243 were skin test positive!

All 66 were recommended to take treatment, but 41 did not. Of these 41, seven developed active disease. None of the Quantiferon negative patients developed active TB. (A stunning result). The Quantiferon test was shown to be 100% sensitive to progression, and requiring only 11% of people (66) to be recommended to take treatment.

By comparison, 40% of the 601 people in the study (243 people) were skin test positive. The sensitivity to progression was 83%, with one person who developed active TB missed by the skin test (but picked up by the Quantiferon test). But also significantly, the skin test result would have required 243 people to take a nine month course of antibiotic treatment, compared to only 66 using the Quantiferon test.

Gambia Study

In this study, the same hypothesis, that IGRA tests are more predictive of active TB infection than the skin test, was sought to be proven, this time using an ELISPOT test. The T-SPOT test from Oxford Immunotec falls into this category but was not used in this study. However there was no difference in progression rates. The conclusion was that the study was flawed for several reasons, including that people in the study remained exposed to people with active TB.

Benefits of Introducing IGRAs

Anja Schablon from **BGW (Accidents Insurance and Prevention in the Health and Welfare Services)** in Germany looked at the benefits of implementing the use of IGRA tests for latent TB screening.

In a study at University Hospital Nantes in France, 85 healthcare workers were screened first with the skin test then with an IGRA test. The study showed that using both tests, 22 unnecessary X-rays could be prevented.

At the same hospital, it was shown that 14 latent TB infections were missed when using the skin test (where a positive result was delivered using a IGRA test).

In a similar contact tracing analysis of 70 healthcare workers over a three year period at University Hospital of Tubingen in Germany, there were 86 unnecessary chest X-rays, where only 3% of the tests were positive for IGRA over this period, compared to 76% positive for the skin test.

The conclusion was that IGRAs should be used in place of skin tests in German healthcare workers, with no X-rays conducted before an IGRA test, and that the number of X-rays of healthcare workers could be reduced using IGRA tests. The IGRA tests are effective in identifying people in close contact with TB actives who would benefit from pharmaceutical preventative care.

Potential Market Size

There are an estimated 9 million people throughout the world with latent TB, and in 2007, there were 1.6 million deaths attributed to infection from this bacterium. In the US, between 10-15 million people have latent TB. Screening for latent TB is conducted in at-risk groups, where confirmed cases are prescribed a nine month antibiotic treatment course, which has shown to be around 50% effective.

IGRA tests, such as the Quantiferon tests, detect both latent and active TB infection, but these tests do not distinguish between the state of infection. Confirmation of active disease is conducted with X-ray of the lungs. The market for latent TB screening is estimated at around 60 million tests a year. For Cellestis, this represents a potential annual market of US$1.2 billion. To date, Cellestis has only penetrated 2.5% of that market.

Cont'd over

Summary - Quantiferon Cemented as Global Test For Latent TB

This was the second symposium on the use of IGRAs for latent TB detection. The first, also sponsored by Cellestis, was held in Vancouver two years earlier. Two years ago the Cellestis Quantiferon test was still somewhat a curiosity for may people working in the TB area. However, according to the company, over the last two years there has been an entrenched acceptance now on the use of IGRAs (both Quantiferon and T-SPOT) in detecting latent TB, either replacing the skin test or being used in conjunction with the skin test. The tipping point for the Quantiferon products we would argue is approaching.

The presentations summarised above have released important data to the TB healthcare community. This includes crucial data on the cost effectiveness of switching to IGRA tests and in particular the Quantiferon Gold In Tube test, the reduction in unnecessary X-rays, the significant reduction in pharmaceutical treatment owing to the higher predictive level of IGRA tests, and the growing number of official guidelines in place around the world recommending the implementation of IGRA tests. The WHO expects to release its own guidelines in 2010. Another advantage of the IGRA tests over the skin test not mentioned over the skin test is that a repeat visit is not required with the IGRA tests.

In our view, the ease of use of the Quantiferon test makes it a far superior commercial product to the T-SPOT test.

Commercial Progress for Cellestis

The Cellestis test is now being used by the San Francisco Health Department, where around 10,000 tests are purchased each year. The New York Health Department uses around 25,000 Cellestis tests a year. Cellestis has a contract in place with Quest Diagnostic, the world leader in diagnostic laboratory testing, and eight of the nine major pathology groups in the US have adopted the test.

The company is currently tracking at selling around 2 million tests a year. This has increased by around 80% in the last year.

Second Product Line in Development

Cellestis is working on a test to detect and monitor the level of immunity to cytomegalovirus (CMV) infection. At least half the world's population has been infected with this virus. Patients undergoing organ transplant are at risk of developing active disease from this virus as a result of immune suppression. These patients are prophylactically medicated whether they have an active immune response to the disease or not.

If they have an active immune response to the infection, there is no need to continue treatment. The Cellestis test under development can measure interferon gamma once again produced by the T-cells but this time in response to CMV. There are around 70,000 organ transplants conducted each year around the world. These patients could benefit from a series of such tests to monitor their immune response post transplant.

The test has shown to work reliably with three studies now published. The company is currently in the process of educating doctors about the benefits of the test. The test is approved for use in Europe and an FDA submission is being prepared.

Patents

Cellestis has at least four families of patents around its technology. The interferon gamma technology patent expires in the US in August 2009. The company also has a patent family granted around the antigen (Quantiferon Gold) which will extend protection out to 2017. The In Tube patent family filed should extend protection out to around 2023. And the company last year filed a patent around a small blood volume finger prick test, which may extend patent life out to 2028. The company also has a patent filed around specific peptides for the CMV test that may deliver protection out to 2022 for that test.

Financials

The company is considering the acquisition of other products or technologies as well as expanding its own pipeline. The company will look to continue to distribute dividends, although a cash balance of around $20 million will be maintained. With the two founders, Tony Radford and Jim Rothel owning 25% of the company, any acquisition of Cellestis will need the consent of the founders.

Cellestis has 52 employees with this expected to increase to 60 shortly.

Cellestis is capitalised at $292 million. At the end of December it had $17.9 million in cash. For the first six months of this financial year the company generated a gross profit of $3.0 million (net $2.85 million with utilisation of tax losses). We are forecasting sales of $38 million for this financial year with a net profit of $5.9 million. This places the company on a forward PE of 50.

We place a **Hold** recommendation on this stock and maintain a very favourable long term outlook for this company. Look for price weaknesses to acquire.

Bioshares

ASX Life Science Sector
Change of Business and Listing Status Analysis 2001-2009 (Prelim)

	Company	Code	Category of Change	Date of change*	Date type*	New, re-named or merged business/Other
	Year ending June 30					
	2001		**67 companies**			
1	Pharmaction	PHD	Change of Business	16/01/2001	Code	Eiffel Technologies
	2002		**76 companies**			
1	Medicine Quantale	MQL	Change of Business	23/08/2001	Code	Cosmos
2	FH Faulding	FHF	Merger	29/11/2001	DL	Merged with Mayne Nickless
3	Analytica	ALT	Change of Business	21/12/2001	ANN	Acquired Psiron's Diagnostic Business
	2003		**80 companies**			
1	Q-vis	QVL	Entered Administration	12/12/2002	EA	Later named Salus Technologies
2	Pi2 Limited	PAI	Change of Business	2/01/2003	Code	Network
3	Provalis	PVL	Expired	10/01/2003	DL	
	2004		**111 companies**			
1	Iatia	IAT	Change of Business	30/09/2003	ANN	
2	Inovax	INX	Change of Business	10/11/2003	Code	Advance Healthcare Group
3	Integra Medical Imaging	IMI	Change of Business	11/12/2003	Code	IM Medical
4	Pan Pharmaceuticals	PPH	Expired	19/12/2003	DL	
5	Analytica	ALT	Change of Business	31/03/2004	EGM	Acquired Brewer Retractable Technologies
6	AGT Biosciences	AGT	Merger	29/06/2004	Code	Merged with Chemgenex Therapuetics
	2005		**119 companies**			
1	Axon Instruments Inc.	AXN	Acquired	9/07/2004	DL	Merged with Molecular Devices
2	Medica Holdings	MCA	Change of Business	20/07/2004	Code	Cytopia
3	Gradipore	GDP	Change of Business	30/12/2004	Code	Name change Life Therapeutics 30/3/04
4	OPSM Group	OPS	Acquired	18/02/2005	DL	Acq. by Luxottica South Pacific
5	Bionomics	BNO	Change of Business	27/06/2005	EGM	Acquired Illiad Chemicals
	2006		**127 companies**			
1	Arrow Pharmaceuticals	AWP	Acquired	13/12/2005	Code	Merged with Sigma Pharmaceuticals
2	Amrad	AML	Demerger	17/12/2005	Code	Avexa formed; name change to Zenyth Th.
3	SSH Medical	SSH	Change of Business	23/01/2006	Code	BioLayer Corporation
4	Cryptome Pharmaceuticals	CRP	Change of Business	16/03/2006	Code	HealthLinx
5	Meditech Research	MTR	Acquired	18/08/2006	DL	Merged with Alchemia
6	Psiron	PSX	Change of Business	28/12/2006	Code	Viralytics
	2007		**130 companies**			
1	Denx	DNX	Expired	29/08/2006	DL	
2	Avastra	AVS	Change of Business	29/08/2006	EGM	Avastra Sleep Centres
3	Zenyth Therapeutiucs	ZTL	Acquired	17/11/2006	DL	Acq. by CSL
4	Salus Technologies	SAH	Change of Business	27/11/2006	Code	Karmelsonix (merger of PulmoSonix and KSI)
5	Gropep	GRO	Acquired	5/12/2006	DL	Acq. by Novozymes
6	Bresagen	BGN	Acquired	8/01/2007	DL	Acq. by Hospira
7	Mayne Pharma	MYP	Acquired	5/02/2007	DL	Acq. by Hospira
8	Cygenics	CYN	Change of Business	19/04/2007	Code	Cordlife
9	Premier Bionics	PBH	Change of Business	28/05/2007	Code	Medic Vision
10	Chemeq	CMQ	Entered Administration	30/05/2007	EA	
	2008		**130 companies**			
1	Acuron Limited	AVP	Change of Business	25/07/2007	Code	Greencap
2	AVT Plasma	AVT	Expired	29/08/2007	DL	
3	Medical Monitors	MDM	Change of Business	12/09/2007	Code	Shell Villages and Resorts
4	Lipa Pharmaceuticals	LIP	Acquired	7/11/2007	DL	Acq. by Apil Healthcare International
5	PanBio	PBO	Acquired	17/01/2008	DL	Acq. by Inverness Medical
6	Medec	MAA	Change of Business	21/01/2008	Code	Atos Wellness
7	Eiffel Technologies	EIF	Change of Business	29/02/2008	Code	Telesso Technologies
8	RiTract	RTL	Change of Business	3/03/2008	EGM	RTL Corporation
9	Visiomed	VSG	Merger	5/03/2008	DL	Avita Medical (merger with Clinical Cell Culture)
	2009		**125 companies**			
1	Evogenix	EGX	Acquired	23/07/2008	DL	Merged with Arana Therapeutics
2	Eqitx	EQX	Change of Business	18/08/2008	Code	Equatorial Coal
3	Ambri	ABI	Change of Business	2/10/2008	Code	Diversa
4	Apollo Life Sciences	AOP	Entered Administration	24/10/2008	EA	
5	Proteome Systems	PXL	Change of Business	19/11/2008	Code	Tyrian Diagnostics
6	Solbec Pharmaceuticals	SBP	Change of Business	5/12/2008	Code	Freedom Eye
7	Life Therapeutics	LFE	Change of Business	19/02/2009	Code	Arturus Capital
8	Ventracor	VCR	Entered Administration	19/03/2009	EA	
9	Advanced Ocular Systems	AOS	Change of Business	5/04/2009	AGM	IFS Construction Services
10	Genesis Biomedical	GBL	Change of Business	4/06/2009	Code	Blackridge Mining

***Abbreviations**

EGM	Extraordinary General Meeting
AGM	Annual General Meeting
EA	Entered Administration
DL	De-listing
Code	ASX Code Change
ANN	Company announcement

ASX Life Science Sector
Change of Business and Listing Status Analysis 2001-2009 (Prelim)

Commentary

As many as 45 listed biotech companies are facing an uncertain future due to extreme tightness in capital markets. Harsh funding conditions have been in effect for more than a year, although the current quarter has proved to be somewhat more favourable for a small number of companies.

What often perplexes biotech investors and observers alike is that many companies seem to linger although they have long since ceased to function as biotech development operations. One reason for this is that a company can maintain a listing for a considerable period of time, by winding down its spend to a hibernation rate of spend of $500,000-$750,000 or so a year. Some companies seem to persist for longer on even less. What often happens to these dormant (shell) companies is that they are re-capitalised by a fresh set of shareholders who either acquire a new business for the entity. This new business may or may not have a biotech focus. A reason so few companies are placed in administration is that there is often not enough in the way cash or assets to make the process worthwhile for the administrators to take on the job.

We have analysed 53 'change of business' events from the ASX life sciences sector for the period FY2001 to FY2009 (to date). We found that only four companies were de-listed as a consequence of corporate non-compliance. Twelve companies were de-listed as a consequence of merger with, or acquisition by another firm. At least four companies went into administration, or continue under administration. The balance changed their business focus, with only ten being used for new non-biotech activities and one company de-prioritised its life science activities. There were twenty one instances of biotech companies refocusing on new biotech activities, and several companies re-focused more than once.

The rate of change ranged from 4%-5% a year (of total listed life science firms) for the period 2002 to 2006, increasing to 7%-8% a year from 2007 onwards to 2009.

The number of dormant or shell companies used as vehicles to list privately held assets is likely to increase in the next twelve months if market conditions improve. If no new biotech listings occur in the next twelve months and the current rate of change of business focus and listing status continues (~8%), then the number of ASX listed biotech companies could be expected to fall to 110 companies if these re-purposed shell companies acquire or invest in non-biotech businesses or assets.

Bioshares

Bioshares Model Portfolio (19 June 2009)

Company	Price (current)	Price added to portfolio	Date added
ASDM	$0.33	$0.30	December 2008
QRx Pharma	$0.40	$0.25	December 2008
Hexima	$0.38	$0.60	October 2008
Atcor Medical	$0.19	$0.10	October 2008
CathRx	$0.45	$0.70	October 2008
Impedimed	$0.62	$0.70	August 2008
Mesoblast	$0.83	$1.25	August 2008
Cellestis	$3.04	$2.27	April 2008
IDT	$1.48	$1.90	March 2008
Circadian Technologies	$0.70	$1.03	February 2008
Patrys	$0.11	$0.50	December 2007
Bionomics	$0.24	$0.42	December 2007
Cogstate	$0.24	$0.13	November 2007
Sirtex Medical	$3.20	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.32	$0.66	September 2007
Starpharma Holdings	$0.31	$0.37	August 2007
Pharmaxis	$2.53	$3.15	August 2007
Universal Biosensors	$0.98	$1.23	June 2007
Biota Holdings	$1.25	$1.55	March 2007
Probiotec	$1.90	$1.12	February 2007
Peplin Inc	$0.61	$0.83	January 2007
Arana Therapeutics	$1.40	$1.31	October 2006
Chemgenex Pharma.	$0.66	$0.38	June 2006
Cytopia	$0.09	$0.46	June 2005
Acrux	$1.23	$0.83	November 2004
Alchemia	$0.37	$0.67	May 2004

Portfolio Changes – 19 June 2009

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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