



Biotech Daily

Daily news on ASX-listed biotechnology companies

To Mavis Tan
December 2, 2012

Response to the Review of ASX Listing Rules Guidance Note 8 Continuous Disclosure:
Listing Rules 3.1 3.1B

There are many things I would like to say about Listing Rule 3.1 and some are contained in the attached editorial (ASX in Wonderland III). But the primary issue that demands immediate change is to provide transparency and a 'level information field' by demanding that companies are not allowed to bury information, as the ASX currently allows.

There have been cases where a material item has been buried on the 6th slide of a 13 slide presentation or the third page of 'an investor update' or worse 'an overseas filing'.

This is not "informing the market" this is "insulting the market".

Sunshine Heart recently proposed a \$28 million capital raising but buried it in an unflagged 'Overseas filing' despite flagging as material a patent announcement and a couple of other far less worthy announcements.

The company said its fear of being seen to tout for funds (in a placement ?) by the US SEC outweighed concerns over the ASX rules.

In any case, the ASX currently accepts that any form of announcement is "informing the market". It certainly is not. Sins of omission are the same as sins of commission. Equal weight needs to be given to negative and positive announcements of the same importance. A successful trial needs to be treated with the same prominence as an unsuccessful trial. The topic of the information needs to be in the title of the company's media release to the ASX.

When Phosphagenics (POH) proudly published its distribution contract with Boots the Chemist in the UK as a stand alone announcement, it should not be able to bury the news (Sep 26, 2012) that Boots had dumped its product on page 6 of a 10 page 'September 2012 Newsletter'. A regulation needs to provide that equal prominence be given, as apologies in newspapers are meant to be given to the original offending article.

When a company has a delay in previously published timelines they need to be stated clearly, not buried in a slideshow.

When a biotechnology company has bad trial results it must not be allowed, as Bionomics did (see Aug 3, 2011 edition, attached), to confound readers by mashing three different trials into one incomprehensible four-page document.

To Starpharma's credit, when the company announced bad news after the market closed on November 28, 2012 it clearly said the drug did not meet its endpoint.

I am well aware of the tricks that companies and their paid PR companies employ to hide news from the vast majority of investors - the Mums and Dads investors - and it is incumbent on the ASX to protect these people.

If you take their money every time they trade and boast about the share-owning Australian community then the ASX has a duty of care to ensure that they are not misinformed or disinformed by the companies spending their investments.

Every ASX release must be comprehensible to one's elderly maiden aunt or uncle, monitoring their superannuation investments. In the 21st Century the majority of Australian investors do not have the time or expertise to parse deliberately misleading announcements, so it is incumbent on the ASX and ASIC to ensure transparency.

If a literate and numerate specialist editor has difficulty under the current system in keeping tabs on companies seeking to bury information, then how can ordinary investors possibly keep up? Listing Rule 3.1 needs to define 'material' and not have the let-out clause of "only if the company considers it material".

Furthermore, the ASX must end the immoral practice of allowing investors to hide behind 'nominee companies'. What are they hiding?

Indeed the spirit (but not the letter) of the Corporations Act refers to a UK inquiry in which it was enshrined that we should be allowed to know our co-investors.

Regulatory Guide 159.270 The substantial holding requirement originates from the recommendations of the Cohen Committee:

"...the intention thereof is to enable a shareholder to know who his co-adventurers are and the public to find out who controls the business to which they are contemplating investment or to which they are considering granting credit": *Report of the Committee on Company Law Amendment* UK (1945) p39.

All substantial shareholders and all large (more than one percent) shareholders need to be identified by the beneficial owner - not some front organization. While I understand the need to protect investors from predators, the rules on share registers simply deter investigations of share registries. Investors should be allowed to see who their co-investors are BEFORE they invest and at no cost.

Yours sincerely,
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Biotech Daily

Wednesday August 3, 2011

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: ANTISENSE UP 25%; OPTISCAN DOWN 22%**
- * **BIONOMICS ENDS MESOTHELIOMA TRIAL; BNC105 'SAFE' IN RENAL CA**
- * **INVESTORS BACK QIAGEN CELLESTIS TAKEOVER**
- * **FDA CLEARS RESONANCE CARDIAC IRON TEST**
- * **FERMISCAN PLACEMENT TO RAISE \$2m; CHANGES DIRECTORS**
- * **UP TO 45% OF VOTES OPPOSE EASTLAND 22.5m DIRECTORS OPTIONS**
- * **NEW EMERGING FUND TAKES 5% OF SUNSHINE HEART**
- * **SUNSHINE HEART APPOINTS GREGORY WALLER DIRECTOR**
- * **DR JOHN DOMAGALA JOINS BIOTA'S SCIENTIFIC ADVISORY BOARD**

MARKET REPORT

The Australian stock market fell 2.27 percent on Wednesday August 3, 2011 with the S&P ASX 200 down 100.8 points to 4332.8 points.

Six of the Biotech Daily Top 40 stocks were up, 21 fell, five traded unchanged and eight were untraded. All three Big Caps fell.

Antisense was the best, up 0.2 cents or 25 percent to one cent with 23.7 million shares traded, followed by LBT up 13.6 percent to five cents with 84,063 shares traded.

Living Cell climbed 8.3 percent; Genetic Technologies and Sirtex were up more than four percent; with Biota up one percent.

Optiscan led the falls, down three cents or 22.2 percent to 10.5 cents, with 51,083 shares traded, followed by Cellmid down 12 percent to 2.2 cents with 457,900 shares traded.

Virax lost 8.7 percent; Alchemia and Bionomics were down more than six percent; Prana, Sunshine Heart and Tissue Therapies were down more than five percent; Nanosonics fell 4.6 percent; Anteo, Benitec, Cathrx, Clinuvel, Impedimed, Pharmaxis, Prima and Viralytics were down more than three percent; Cochlear, CSL and QRX shed more than two percent; with Acrux, Mesoblast and Starpharma down more than one percent.

BIONOMICS

Bionomics says it will discontinue its planned 60-patient phase II trial of BNC105 for mesothelioma after one of 24 patients had an objective response.

Bionomics said the planned 134-patient, phase II trial of the vascular disrupting agent BNC105 for renal cell carcinoma would continue with the dose-ranging part of the trial showing safety and tolerability.

In a four-page announcement combining information about the two trials and a proposed BNC105 ovarian cancer trial, Bionomics said the mesothelioma trial “yielded important information which will be valuable for future development partners of BNC105”.

Bionomics said that in renal cell carcinoma patients, BNC105 was well-tolerated at a dose of 12.6mg/m² when administered in combination with Afinitor and “individual patients” had received 12 cycles or more of treatment with BNC105 in combination with Afinitor.

The company said the result was “a key milestone ... as 12.6mg/m² is a dose that gives rise to reduced tubulin polymerization, the therapeutic target of BNC105”.

Bionomics said it expected to complete enrolment of 134 patients in the renal cell carcinoma trial by the end of 2012 and there were nine US clinical centres recruiting patients with 12 more sites to be initiated by October 2011, but the company provided no efficacy data from the phase II trial which began last year (BD: Jan 27, 2010).

A journal article, entitled ‘Clinical, Pharmacodynamic, and Pharmacokinetic Evaluation of BNC105P: A Phase I Trial of a Novel Vascular Disrupting Agent and Inhibitor of Cancer Cell Proliferation’ published in *Clinical Cancer Research* on August 1, 2011 and co-authored by Bionomics’ drug development director Dr David Bibby and head of research and development Dr Gabriel Kremmidiotis, said the drug was well-tolerated at 16mg/m² in mesothelioma patients.

The abstract is at: <http://clincancerres.aacrjournals.org/content/17/15/5152.short?rss=1>.

Bionomics said the mesothelioma trial was a single arm, phase II trial including patients progressing after first line chemotherapy with pemetrexed (Alimta) and cisplatin and an interim analysis of the safety, tolerability and response rate had been completed with a 16mg/m² dose of BNC105 well-tolerated in the 24 patients evaluated.

Bionomics said that one patient showed a 57 percent reduction in tumor measurement, which was classified as an objective response and the patient remained on BNC105 treatment with a clear, durable response.

The company said that “at least five patients have been to date classified as having stable disease according to [Response Evaluation Criteria In Solid Tumors] for mesothelioma”.

“Based on this analysis there will be no further enrolment into the current trial,” Bionomics said.

University of Western Australia Faculty of Medicine’s Dr Anna Nowak and principal investigator said “the objective tumor response, safety profile and tolerability of BNC105 warrant further research into its integration with established chemotherapy regimens”.

Bionomics chief executive officer Dr Deborah Rathjen said that “based on the findings of this trial and on our preclinical evidence of encouraging combination data with cisplatin, Bionomics is considering development of BNC105 for the treatment of mesothelioma as first line therapy in combination with Alimta and Cisplatin.”

Bionomics said it was planning to evaluate BNC105 in combination with carboplatin and gemcitabine in a multi-centre randomized phase I/II trial in women with ovarian cancer in Australia and the US to begin by July 2012.

Bionomics said encouraging data in a single arm phase II ovarian cancer trial had been reported with Zybrestat and BNC105 was thought to be more potent and selective.

The company said it had the funds to run the trials.

Bionomics fell four cents or 6.25 percent to 60 cents.

CELLESTIS

Cellestis says shareholders have overwhelmingly voted to support the proposed acquisition by Qiagen NV (BD: Apr 4, Jul 11, 2011).

Cellestis said that more than 80.8 percent of votes and up to 92.39 percent of votes supported all resolutions including approval of changes to the proposed dividend and scheme consideration.

The company said shareholders would receive \$3.80 cash per share less the cash amount of the special dividend, if it is declared to be paid by the Cellestis board.

Cellestis said the scheme consideration was expected to be paid by September 1, 2011, with the dividend and other matters to be announced at a later date.

Cellestis was in a trading halt and last traded at \$3.76.

RESONANCE HEALTH

Resonance says the US Food and Drug Administration has given 510(k) clearance to market its cardiac iron test, MRI-Q, in the United States.

Resonance said the test measured a magnetic resonance imaging parameter known as cardiac T2* (a measure of echo time) which was highly sensitive to cardiac iron loading.

Resonance said it received Health Canada approval for the test in July 2011 along with Australian Therapeutic Goods Administration and Conformité Européenne (CE) mark approvals in 2010.

The company said it had received considerable demand for the cardiac T2* iron test from its existing US customers and expected strong uptake in this market.

Resonance said cardiac iron overload was the major cause of death in beta-thalassaemia major patients.

The company said that a service to provide an accurate non-invasive test for both liver and cardiac iron measurements would be made available to clinicians, offering significant improvement to patient management and outcomes.

Resonance said it would also explore opportunities to provide the test to clinical trials concerned with the assessment of iron overload therapies.

Resonance was unchanged at 1.9 cents.

FERMISCAN HOLDINGS

Fermiscan says it has a mandate with Capital Investment Partners to place 571,428,571 shares at 0.35 cents per share to raise \$2,000,000.

Fermiscan said it had agreed to issue a further 160,000,000 options exercisable at one cent each by December 31, 2011 at an issue price 0.05 each to raise \$80,000.

The company said it had subscription sums of \$262,500 and had allotted and issued 75,000,000 Shares under the 15 percent placement capacity, with the balance of 496,428,571 shares and 160,000,000 options subject to shareholder approval.

Fermiscan said the funds would be for Italian and French trials of the Prof Veronica James invented x-ray diffraction of hair test to detect breast cancer and the identification of any potential new businesses and to provide working capital.

Fermiscan has previously said it does not own the intellectual property to the test that has not shown significant accuracy or reliability (BD: Jan 16, 2011).

Separately, Fermiscan said it had appointed Richard Wright and Charlie Bontempo as non-executive directors replacing Ian Chalmers and Ben Dillon, effective from today.

Fermiscan was up 0.3 cents or 37.5 percent to 1.1 cents with 9.1 million shares traded.

EASTLAND MEDICAL SYSTEMS

Eastland shareholders voting at and extraordinary general meeting have shown significant dissent against resolutions to give directors up to 22,500,000 options (BD: Jul 1, 2011). All resolutions were passed but there was strong dissent against the issue of options to directors Peter Jooste, Michael Stewart and Stephen Carter.

The closest vote saw 13,737,211 proxy votes (45.0%) oppose the issue of 7,500,000 options to Mr Jooste with 16,795,252 proxy votes (55.0%) in favor.

Other resolutions to issue smaller parcels of shares to Mr Jooste were passed more easily, as was a resolution to issue 98,145,130 options which was opposed by about four million proxy votes and supported by about 26 million proxy votes.

Eastland has 594,394,120 shares on issue implying 2.3 percent of shares voted against the option issue to Mr Jooste.

Eastland was unchanged at 2.5 cents.

SUNSHINE HEART

The New Emerging Opportunities Fund has become a substantial shareholder in Sunshine Heart with the acquisition of 62,500,000 shares or 5.5 percent of the company. The initial substantial shareholder notice said the Montreal, Quebec fund acquired the shares for \$2,500,000 or four cents a share.

Separately, Sunshine Heart said it had appointed Gregory Waller as a non-executive director.

Sunshine Heart said that Mr Waller had more than 30 years of financial management and industry experience, with an established history of serving on the boards of several successful medical device companies.

The company said he was the second US-based director to be appointed this year following the appointment of Paul Buckman in January.

Sunshine Heart said Mr Waller was previously the chief financial officer of Sybron Dental Specialties until he retired in 2005.

The company said Mr Waller contributed to the company's growth from \$10 million to \$750 million in sales and served in operational and financial management positions.

Sunshine Heart said Mr Waller was a director of Endologix, which developed and manufactured minimally invasive treatments for vascular disease.

Sunshine Heart fell 0.2 cents or 5.3 percent to 3.6 cents with 1.1 million shares traded.

BIOTA HOLDINGS

Biota says it has appointed Dr John Domagala to its scientific advisory board.

Biota said Dr Domagala had more than 30 years experience in pharmaceutical anti-infective research and had held senior management positions in the US pharmaceutical industry, including as Pfizer Global Research's executive director of infectious diseases and a senior director at Warner-Lambert Park Davis.

The company said Dr Domagala held a PhD in medicinal chemistry and had led teams in every aspect of drug discovery and development with successful progression of 10 prospective drugs into clinical development and three new drug applications and previously acted as a Biota advisor, including during the acquisition of Prolysis assets.

Biota was up one cent or one percent to 97 cents.



Biotech Daily

Thursday June 25, 2009

Editorial: ASX In Wonderland III; Corporate Regulation

Biotech Daily believes the regulation – or lack of regulation - of Australian listed companies needs a dramatic overhaul. The system has failed. The material below has been sent to Finance Minister Lindsay Tanner and the Minister for Corporate Law, Chris Bowen.

ASIC & ASX

The roles of the ASX and ASIC need to be reappraised. Neither organization is effective in policing the corporate sector. Despite a few high profile cases to salve the anger of its elected masters, ASIC is as anti-transparency as the companies it prosecutes. It is frustrating to report wrong-doing to ASIC only to be told the organization can't comment on cases - until the public relations cycle suits it. ASIC is behaving like a bad police force, pretending to solve crime when nothing is being done. If the organization is actually doing work then it should be able to say so.

The primary criticism from former investigators is the lack of funding. It is an old political confidence trick, that one inherits a powerful regulator and then merely fails to fund operational staff. The Australian Government says it has increased funding to ASIC, but there has been no increase in transparency or prosecutions. There needs to be a review of the qualifications and ability of investigating staff to ensure that sufficient people capable of tracking corporate crime are on the payroll.

As for the ASX, it is a developed world joke that the broking houses' collective, earning income on every single share trade, is the regulator of the broking houses and their trades. This is a conflict of interest. A new regulator is required.

The ASX attempts to monitor/police its member companies, but claims it is powerless to do so. It wastes resources tracking directors of innocent companies who are a day late with their Directors Interest Appendix 3X, 3Y and 3Z statements, but lets crooks operate without let or hindrance. Recently, the ASX asked a dead director and company secretary why he didn't file his final Appendix 3Z statement.

THE LISTING RULES

The Listing Rules are best described by Captain Barbossa (Geoffrey Rush) in *Pirates of the Caribbean*, referring to the Pirates Code, as "more guidelines, than your actual regulations".

The most basic concept of the listing rules, namely what is 'material' is not defined, nor – according to the ASX - has it ever been tested in court. Listing Rule 3.1 on transparency effectively says matters are material if they are of the nature of a dozen examples, but only if they are material; which is why we have headlines reading 'ASX in Wonderland'. The same is the case for 'fair and reasonable'.

If there is no definition of what is 'material' nor 'fair and reasonable' then how is anyone to know what is required? In any case the 'guideline' of material affecting profit expectations by more than 15 percent is a furphy. CSL does not need to say it has won a \$10 million Government grant, because that amount is immaterial to a \$20 billion company. But not to taxpayers and investors and not to companies whose market capitalization is \$5 million!

ASX & ADMINISTRATORS

In the current case of the administration of Ventracor, it has been demonstrated that the ASX is powerless to enforce its own guidelines when faced with a single obstinate accountant. Ventracor was placed into voluntary administration with Ferrier Hodgson. Ventracor is (at the time of writing, still) a publicly listed company. The sale of all of its assets would by any measure be considered 'material'. But Ferrier Hodgson has told Ventracor shareholders nothing. It has posted several notices on its own website, but none have been posted to the ASX.

Again, the ASX says it is powerless to do any more than 'have a word' with Ferrier Hodgson, whose primary duty is to creditors, not shareholders. However, as the body legally responsible for Ventracor, the administrators should be held to be legally responsible to at least inform Ventracor shareholders of their actions. This can be fixed with a simple amendment to existing legislation requiring administrators to keep shareholders informed of any decision that could impact on their holdings or the remnants thereof. It would be better to revisit the entire Corporations Act and ASX Listing Rules.

ASX AND DATA PROVISION

The ASX also fails – through sloth – to inform shareholders of a most essential piece of company data – the correct market capitalization of a company.

Biotech Daily first raised this matter in 2004 and despite promises from the then head of the communications department, nothing has been done.

There are two distinct and easily-solved problems, but instead of dealing with the issues, the ASX simply does nothing.

SHARES IN ESCROW

Shares held in escrow are withheld from trading for a variety of reasons. However they have the full legal power to vote in general meetings and partake in rights issues and are worth the same as a tradeable share. This was demonstrated last month when Nanosonics released 97 million escrowed shares instantly doubling its ASX reported market capitalization. The correct figure should have been available all the time.

It is the bane of small companies that the ASX cannot be bothered publishing correct data. The ASX promised that at the next computer update, then expected at the end of 2005, the system would be updated to include shares in escrow to give the correct market capitalization. An investor using data from the ASX will find many smaller companies with an incorrect market capitalization due to this ASX failure. It discriminates against the younger, smaller companies, because most older companies don't have shares in escrow.

FOREIGN HOLDINGS

In one of the best pieces of dissembling I have ever heard, the present head of ASX communications told Biotech Daily that it was not the ASX's responsibility to count shares held and traded off-shore. Hence Resmed, according to the ASX, has a market capitalization of just \$700 million, when the real figure is \$3.5 billion. Peplin and Psivida are discounted by about 50% by the ASX, which claims to be incapable of doing what some companies themselves do and publish a real-time total market capitalization.

The ASX's job is to ensure an orderly market place, but it does not seem capable of publishing accurately the most important data. It is often out of date with lists of directors and other data. Resolving this data problem is not difficult. The companies with offshore trading can report their total holdings to the ASX in equivalence to Australian shares and the ASX can provide the market capitalization. The ASX needs a lesson in transparency and equity.

TRANSPARENCY

Finally, the present legal framework allows every unsavory and/or criminal operator to hide behind the concept of 'nominee' companies. If one reads the Top 20 shareholders of a company in its annual report – that is, who owns and runs the company – more often than not one learns nothing because the major shareholders are hidden under 'National Nominees', 'Commonwealth Custodians', 'Merrill Lynch Nominees' and other such mysterious entities. Apparently it is a system encouraged by the nominee companies to provide them with both large accounts (and account-keeping fees) and to provide power over the listed companies in whom they maintain the collective holding.

It is the precise opposite of transparency and I have heard no reasonable argument in support of this system. If Al Capone holds 22% of the Helpful Taxation Tips Co, with Edward Kelly (19%) and Ronald Biggs (15%) but they all hide under Honest Nominees (56%) then most investors might think the company benign, when it is not.

One company director said he needed to hide his holdings to prevent the Australian Taxation Office and his wife knowing how much he was worth. I think this is the main use of nominee companies. The paper trail from publicly-listed companies should be open and transparent and where there are related parties, the investors should be compelled to link them. A substantial shareholder notice for Cogstate (BD: May 29, 2009) from the Myer Family was exemplary in its openness. If the Myer Family can do it, anyone can.

The same needs to be the case with daily share transactions. Who needs to hide their identity unless there is something underhanded? Until recently brokers were able to tell which broking house was selling and buying and could even determine some buyers. In the interests of transparency the ASX shut down the one mechanism which could explain some unusual trading.

Ordinary shareholders have enough difficulty understanding the machinations of our 2000 listed companies, without the alleged gatekeeper, the ASX, further obfuscating important data and information.

The ASX should be entirely relieved of any role in regulation and a proper regulatory regime established along with an information system designed to benefit ordinary investors and not just "the big end of town". Anything less is a discriminatory disservice to all investors.

These proposed changes would be good for business and good for investors. Everyone benefits from transparency and equal treatment.

David Langsam
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