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 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 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.