Biotech Daily

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Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: LABTECH UP 20%, POLARTECHNICS DOWN 17%**

*** BIOGUDE BRIEF: WHO CONTRIBUTES TO SOLAGRAN'S SHARE PRICE?**

*** CIRCADIAN, HEALTHSCOPE $10m DEAL ON PETER MAC DIAGNOSTIC**

*** COGSTATE $1.3m MAIDEN H1 PROFIT ON REVENUE UP 135% TO $3.9m**

*** NOVOGEN PHASE IIa PROSTATE CANCER TRIAL SAFE, SOME EFFICACY**

*** MESOBLAST LOW-DOSE STEM CELLS SAFE IN CARDIAC TRIAL**

*** GFC KILLS $2m CHINESE INVESTMENT IN POLARTECHNICS**

*** HEALTHLINX NEARS INEX DEAL FOR ASIAN DISTRIBUTION**

*** CYTOPIA URGES PROGEN INVESTORS TO OPPOSE AVEXA MERGER**

MARKET REPORT

The Australian stock market fell 0.1 percent on Wednesday February 25, 2009 with the S&P ASX 200 down 4.1 points to 3,327.5 points.

Nine of the Biotech Daily Top 40 stocks were up, 15 fell, 10 traded unchanged and six were untraded.

Labtech was best, up two cents or 20 percent to 12 cents with 80,000 shares traded, followed by Optiscan up 11.1 percent to five cents and Circadian up 10.5 percent to 74 cents.

Cellestis climbed 9.5 percent; Starpharma was up 5.9 percent; Arana Genetic Technologies and Heartware rose more than two percent; with Mesoblast up 1.27 percent.

Polartechnics led the falls, down two cents or 16.7 percent to 10 cents with 336,167 shares traded, followed by Tyrian down 16 percent to 2.1 cents.

Peplin lost 14.3 percent; Phosphagenics fell 13.3 percent; Chemgenex lost 11.4 percent; Clinuvel was down 7.1 percent; Universal Biosensors fell 5.66 percent; Novogen fell 4.6 percent; Alchemia and Progen were down more than three percent; Acrux, Benitec, Biota and Sirtex shed more than two percent; with Impedimed down 1.39 percent.

MARC SINATRA'S BIOGUIDE BRIEF: SOLAGRAN'S CONTRIBUTING SHARES

It has been a painful trip down for Solagran shareholders from highs of more than $1.50 a share down to today's 10.5 cents and a low of nine cents on February 23. Solagran has not seen these levels since it hit 8.5 cents on June 11, 2004.

While shareholders probably lay most of the blame for this share price slide on Solagran itself for failing to generate any volume sales of its medicine Ropren so far, Solagran directors say it is the shareholders themselves who are causing the current round of share price weakness.

"The sell down of ordinary shares by the contributing shareholders – presumably to raise money to pay the call – has been the main factor causing the decline in the price of ordinary shares," Solagran told the ASX on February 12, 2009.

Solagran is one of only a few companies who have contributing or partly-paid shares, which traded under the code SLACF and now trade under the code SLAN, in addition to standard fully-paid ordinary shares.

With contributing shares, the investor initially pays only a percentage of the issue price for the share. In the case of Solagran's SLANs, investors originally paid one cent per 20-cent contributing share - the price per ordinary share of the 2003 capital raising.

In a rising market, contributing shares – like options – allow investors to access full price appreciation with payments over time. When the market falls, both contributing shares and options can lose their gloss, except options don't carry an overhanging debt.

Along with the contributing shares, however, the investor also gets the legal obligation to pay the outstanding monies owed on it based on a schedule proposed by the company directors. Since being listed, the contributing shares have had several calls made on them, such that they are now paid up to 15 cents.

The final five cent payment on Solagran's 47 million SLACF's is due on March 2, 2009.

In the meantime, contributing share-holders must find the money to meet the call.

Now, the directors believe that many contributing share-holders who also hold ordinary SLA shares are selling ordinary shares to pay for the call and, consequently, are pushing down the share price.

Solagran shareholders are now legally bound to pay five cents on top of the 15 cents they have already paid, in order to convert their contributing shares to ordinary shares currently trading at nine cents - or forfeit the shares.

SLACFs last traded at six cents on February 16 when they became SLANs which have not traded.

Solagran's ordinary shares fell half a cent or 4.55 percent to 10.5 cents.

CIRCADIAN TECHNOLOGIES

Circadian has signed a potential $10 million deal with Healthscope to commercialize a diagnostic technology for 'cancers of unknown primaries'.
Circadian said cancers of unknown primaries were tumors which are found in one organ of the body which originated and metastasized from a different organ.
The company said they were "a challenging form of cancer in which the site of origin of a tumor cannot be identified using standard techniques".
The diagnostic method was developed in collaboration between Circadian and Melbourne's Peter MacCallum Cancer Centre.
Circadian said the potential $10 million deal was the largest deal seen between an Australian biotechnology company and an Australian health operator.
Circadian chief executive officer Robert Klupacs told Biotech Daily his company could earn up to $10 million from licence fees and royalty payments.
In its media release to the ASX Circadian said Healthscope through its subsidiary, Clinical Laboratories, would further develop, clinically validate and market the test throughout Australia, New Zealand, Malaysia and Singapore.
Circadian would retain rights to market the test in the rest of the world.
Healthscope will pay Circadian an upfront fee, development milestones and a royalty on sales of the test.
Circadian, through wholly-owned subsidiary Cancer Therapeutics, owns exclusive global rights to the test through a licence with the Peter MacCallum Cancer Centre.
The cancers of unknown primaries diagnostic methodology identifies a patient's tumor type by comparing its pattern of gene expression to a database of known tumors.
By correctly identifying a patient's tumor type, clinicians can develop a more effective treatment strategy for the cancer.
Circadian managing director Robert Klupacs said the cancers of unknown primaries diagnostic test was the result of a four-year collaboration between Circadian and the Peter MacCallum Cancer Centre.
He said the diagnostic was "an important adjunct to Circadian's core focus as a developer of novel antibody-based drugs to treat cancer".
Healthscope's molecular division scientific director Dr Keith Byron said the methodology added to his company's "existing focus on developing diagnostic tools for doctors".
Peter MacCallum Cancer Centre director and a co-inventor of the diagnostic methodology Dr David Bowtell said cancer of unknown primary cause was "actually the fourth most common cause of cancer deaths in Australia".
"We hope the assay will lead to earlier diagnosis, improved treatment outcomes and enhanced quality of life for patients," Dr Bowtell said.
Circadian said there was a large potential global market.
In 2007, the American Cancer Society estimated that 32,100 people would be diagnosed with cancers of unspecified primary sites for that year.
Circadian was up seven cents or 10.45 percent to 74 cents.

COGSTATE

Cogstate says it has recorded its maiden profit of $1.29 million for the six months to December 31, 2008 on revenue up 135 percent to $3.92 million.
Cogstate said it expected to have revenues of $3.0 million to $3.5 million in the six months to June 30, 2009 and forecast a net profit after tax in the range of $1.50 million to $1.75 million for the year ending June 30, 2009.
Cogstate was up two cents or 10 percent to 22 cents.

NOVOGEN

Novogen says preliminary results from a phase IIa clinical trial of oral phenoxodiol in patients with prostate cancer has shown safety and “some evidence of clinical activity”.

Novogen said the research was led by Yale Cancer Center solid tumor investigation associate director Dr Kevin Kelly.

The company said the data would be presented at the American Society of Clinical Oncology Genitourinary Cancers Symposium in Orlando, Florida, February 26-28, 2009 and would be available on-line in abstract form.

The abstract relates to a poster presentation which will review data supporting the anti-tumor effects of phenoxodiol as studied in patients with advanced prostate cancer (Group A) and in patients with early stage, pre-metastatic disease where prostate specific antigen levels were rising after radical prostatectomy or radiation therapy (Group B).

Twenty five patients have been treated to date; 16 in Group A and nine in Group B.

Interim analysis shows that among Group A patients, one remains on therapy without disease progression for greater than six months and one patient had a greater than 50 percent post-therapy prostate specific antigen PSA decline, while five patients in Group B had stable disease for a median time of three months.

“Oral phenoxodiol was very well tolerated with no severe adverse events reported to date,” Dr Kelly said.

“More importantly, we observed some evidence of clinical activity, especially in the early stage disease group, in terms of holding disease progression in check” Dr Kelly said.

“Further studies evaluating the impact of phenoxodiol on serum cytokines will be explored at the completion of the trial,” he said.

Novogen said that in a related development concerning the potential for phenoxodiol as a therapeutic in prostate cancer, a paper had been published in the British Journal of Cancer reporting that, in addition to its potential as a single agent therapeutic, phenoxodiol was able to enhance the activity of cisplatin and carboplatin against prostate cancer cells in vitro.

The study was conducted at Sydney’s St George Hospital by Prof Paul de Souza and colleagues of the Department of Medical Oncology.

Novogen said the study concluded “that phenoxodiol has interesting properties that make combination therapy with cisplatin or carboplatin appealing”.

Novogen said Phenoxodiol was being developed by the US based Marshall Edwards as a chemosensitizing agent in combination with platinum drugs for late stage, chemo-resistant ovarian cancer and as a monotherapy for prostate and cervical cancers.

Novogen owns about 70 percent of Marshall Edwards.

It has a unique mechanism of action, binding to cancer cells via a surface oxidase, causing major downstream disturbances in expression of proteins necessary for cancer cell survival and responsible for the development of drug resistance.

In cancer cells, phenoxodiol appears to selectively inhibit the pro-survival regulator known as S-1-P (sphingosine-1-phosphate) that is over-expressed in cancer cells.

The company said that In response to phenoxodiol, the S-1-P content in cancer cells is decreased, rendering those cells more sensitive to chemotherapy.

Novogen said that in laboratory studies, it had been demonstrated that cancer cells pre-treated with phenoxodiol were killed with lower doses of chemotherapy drugs.

Novogen fell three cents or 4.62 percent to 62 cents.

MESOBLAST

Mesoblast says the absence of any cell-related adverse events in the first patient cohort treated with Revascor for congestive heart failure is a “key safety milestone”.

Mesoblast said Revascor was a proprietary allogenic or off-the-shelf adult stem cell therapy being developed to reverse congestive heart failure by rebuilding both blood vessels and heart muscle.

The company said the cells had been implanted in 20 congestive heart failure patients enrolled in the multi-centre phase II clinical trial by Mesoblast’s US-based sister company Angioblast Systems.

The company said the data had been reviewed by the trial’s data safety and monitoring board, as mandated by the US Food and Drug Administration.

“No cell-related adverse events occurred in any patient during the 30-day follow-up period and the review was positive,” Mesoblast said.

The company said that as a result, the monitoring board had allowed it to recruit the second 20-patient cohort of patients with congestive heart failure, which will receive a higher dose of cells.

Mesoblast said the placebo-controlled trial of Angioblast’s Revascor cell therapy would randomize up to 60 patients with congestive heart failure to three 20-patient cohorts receiving either a progressively increasing dose of the company’s allogeneic adult stem cells or standard of care.

The company said the cells would be implanted into the damaged heart muscle using the Noga Myostar catheter technology system provided through a collaborative agreement with Johnson & Johnson companies, Biologics Delivery Systems and Cordis Cardiology.

The outcomes in each patient group following injection of progressively increasing doses of cells will be compared against standard-of-care in terms of both safety and effectiveness at halting or reversing congestive heart failure.

The company will provide interim results for each dose cohort as they become available.

Mesoblast and Angioblast executive director Prof Silviu Itescu said he was very encouraged by the safety profile of Revascor to date.

“Patient recruitment has proceeded in a very rapid manner, reflecting both the excellent safety profile of our cells and the ease of delivery of an allogeneic cell therapy in this very ill patient population in serious need of effective new treatments,” Prof Itescu said.

Mesoblast was up one cent or 1.27 percent to 80 cents.

POLARTECHNICS

Polartechnics says a placement of $2 million of ordinary equity to China’s Beijing Unisplendour Junchuang Medical has failed, due to the global financial crisis.

Polartechnics said dialogue continued with the Chinese group which has “indicated they are still interested in investing in the company in the future”.

Polartechnics said Chinese government approval for the investment was not forthcoming “due to government policy changes, which encourage domestic, rather than international investment”.

“This is a direct result of the global financial crisis and its impact in China,” Polartechncis said.

Polartechnics said its share purchase plan (BD: Feb 24, 2009) had the potential to replace the capital expected from the Chinese placement.

The company said it was continuing discussions with potential investors for an alternative private placement.

Polartechnics fell two cents or 16.7 percent to 10 cents.

HEALTHLINX

Healthlinx says it has reached commercial terms with Inex for a 10-year exclusive contract to distribute the Ovplex early stage ovarian cancer diagnostic in Asia.

Healthlinx said the Singapore-based Inex would have exclusive rights for 10 years to use, market, sell and distribute Ovplex in Singapore, Malaysia, Vietnam and Thailand with first rights to India and other Asian countries along with options for a further 10 years.

Healthlinx said it would "pursue the execution of a formal distribution agreement with Inex pursuant to the commercial terms agreed".

Inex chairman Prof Mahesh Choolani said ovarian cancer was "the most common gynaecological malignancy in Singapore and a rapidly growing problem throughout Asia".

"Early detection of ovarian cancer is paramount to better the survival of affected women, usually in the prime of their lives," Prof Choolani said. "Prior to Ovplex there was no effective detection method for early ovarian cancer."

Healthlinx said Ovplex had a diagnostic efficiency of 92.9 percent for early stage ovarian cancer.

Healthlinx managing director Nick Gatsios said the Asian market was "an attractive opportunity for Ovplex with its burgeoning middle class economy and increasing demand for better medical products".

Mr Gatsios told Biotech Daily he expected first sales within six months.

Healthlinx fell 0.1 cents or 1.59 percent to 6.4 cents.

CYTOPIA, PROGEN, AVEXA

Cytopia has written to Progen shareholders urging them to vote against the proposed Avexa merger.

Cytopia said if Progen shareholders were not attending the meeting they should appoint Cytopia chief executive officer Andrew Macdonald as their proxy.

In the on-going war of words over the two alternative merger proposals (BD: Dec 22, 2008; Jan 28, 2009) Cytopia said the Progen board reluctantly responded to its request for a meeting and called a second meeting for March 27, 2009 where only the board replacement resolutions would be put to shareholders.

Cytopia said that at the March 11, 2009 Progen Avexa merger meeting, the Cytopia group would "put forward a motion to adjourn the meeting until immediately after the March 27, 2009 meeting".

Cytopia said it opposed a Progen merger with Avexa because the proposed share buy-back would be capped at $20 million; the board proposes a long, costly phase III program, in HIV; the Avexa HIV drug development costs are estimated at $155 million to complete the phase III program and the drug may take four years to reach registration; without partnering the merged entity would need another $95 million; and the HIV drug had failed to attract a partner with competition from new classes of HIV drugs.

"As the current Progen board is not supporting a share buy-back without the Avexa merger, we recommend you vote against all of the resolutions," Cytopia said.

Cytopia was untraded at nine cents

Progen fell 2.5 cents or 3.0 percent to 80 cents

Avexa was unchanged at 6.9 cents.