Biotech Daily

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Daily news on ASX-listed biotechnology companies

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*** SINGAPORE GRANTS $772k TO ROCKEBY RESEARCH**

*** HEARTWARE SHARES, CODE CHANGES**

MARKET REPORT

The Australian stock market recovered 1.3 percent on Wednesday October 29, 2008 with the All Ordinaries up 50.4 points to 3,805.8 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 13 fell, three traded unchanged and 11 were untraded.

Benitec was best, up 1.7 cents or 42.5 percent to 5.7 cents with 329,500 shares traded, followed by Optiscan up one cent or 20.00 percent to six cents, Cytopia up 18.18 percent to 13 cents and Viralytics up 12.5 percent to 4.5 cents.

Biota, Clinuvel and Pharmaxis climbed more than six percent; Mesoblast was up 5.39 percent; Cellestis, Chemgenex and Labtech were up four percent or more; Arana, CSL and Progen rose more than three percent; with Cochlear up 2.74 percent.

Living Cell led the falls, down 3.5 cents or 17.95 percent to 16 cents, followed by Alchemia down 11.43 percent to 15.5 cents and Phosphagenics down 10.45 percent to six cents.

Starpharma lost 9.09 percent; Heartware, Psivida and Sirtex fell more than eight percent; Peplin lost 7.89 percent; Neuren fell 5.66 percent; Stem Cell and Universal Biosensors shed more than four percent; with Resmed and Ventracor down more than one percent.

NOVOGEN

Novogen says studies of NV-128 with Marshall Edwards' phenoxodiol produce potent synergistic anti-cancer activity against non-small cell lung carcinoma cell lines.

Novogen said the pre-clinical data was presented by Novogen's cancer biology program manager Dr David Brown at the 9th International Conference on Membrane Redox Systems in Wellington. New Zealand.

The company said the synergistic cytotoxicity observed between NV-128, a novel mTOR inhibitor and phenoxodiol was superior to the synergy observed between NV-128 and paclitaxel against non-small cell lung carcinoma.

Dr Brown said that in non-small cell lung carcinoma targets, the two drugs in combination produced an anti-cancer effect superior to that achieved with either drug alone or in combination with current approved anti-cancer cytotoxic drugs.

"The potential for improved efficacy, coupled with the safety profile of these novel drugs, suggests the potential for clinical benefits in lung cancer patients which cannot be achieved with current standard of care drugs," Dr Brown said.

Novogen said Phenoxodiol is being developed by its 72 percent subsidiary Mrashall Edwards as a therapy for late -stage, chemo-resistant prostate and ovarian cancers.

The company said it was "a novel-acting drug that inhibits key pro-survival signaling pathways operating via sphingosine-1-phosphate and Akt.

Inhibition of these pathways leads to prevention of phosphorylation of key anti-apoptotic proteins such as XIAP and FLIPs, Novogen said.

Loss of activity of these proteins restores the ability of chemo-resistant tumor cells to undergo caspase-mediated apoptosis in response to chemotherapy.

The putative molecular target for phenoxodiol is a surface oxidase which is preferentially expressed on cancer cells and is linked to the expression of pro-survival pathways in these cells.

The ability of the drug to bind preferentially to cancer cells rather than normal cells is reflected in its high safety profile in clinical use.

Novogen said that in contrast to phenoxodiol, NV-128 did not induce caspase-mediated apoptosis, a death mechanism which is often non-functional in chemoresistant cancer cells due to accumulated mutations in tumour suppressor/promoter genes and over-expression of anti-apoptotic proteins.

Rather, NV-128 uncouples the akt-mTOR-P70S6K signal transduction cascade which has a key role in driving protein translation and uncontrolled cancer cell proliferation.

Further, NV-128 induces mitochondrial depolarisation via a novel pathway involving the autophagy protein Beclin-1 and Bcl-2, thereby resulting in endonuclease G translocation to the nucleus and cell death.

Importantly, when NV-128 is used in combination with phenoxodiol, XIAP is degraded in these cells allowing the caspase-mediated apoptosis cascade to be engaged in addition to NV-128-endonuclease G mediated apoptosis resulting in two pathways to cell death.

"These data provide direct evidence that while invoking discrete modes of cell death, NV-128 and phenoxodiol can be used synergistically to force the convergence of caspase-mediated and caspaseindependent cell death pathways to drive overall cell death," Dr Brown said.

Novogen fell half a cent or 0.52 percent to 95.5 cents.

BIOTA

Biota's board faced tough shareholder questions on its handling of the case against Glaxosmithkline as well as the granting of options to chief executive officer Peter Cook.

A range of shareholders questioned the board's decision-making and communication skills with questions and criticism coming from shareholders including the Hunter Hall Global Value deputy chairman Jack Lowenstein, Bioshares editor David Blake and this writer, Biotech Daily editor David Langsam.

The Biota meeting may be a harbinger of things to come at many annual general meetings as shareholders express concern over perceived company failures and especially the awarding of incentives to management and staff at a time of sharply falling share prices.

The counting of proxy votes was also closely questioned, following chairman John Grant's announcement on October 24, 2008 that he would change the direction of open proxy votes from the advice sent to shareholders a month earlier.

Many Biota shareholders did not receive written notice of the change prior to the meeting, although it was reported to the ASX and published in Biotech Daily.

Mr Grant said he had changed his mind on the election of Dr Michael Montalto as a director and directed open proxy votes against the candidate.

Mr Grant told the meeting that Glaxosmithkline had offered $75 million to end the legal case over the Relenza anti-influenza drug in October 2006.

He said the decision to continue the case, then accept $20 million this year were unanimous board decisions.

Several shareholders raised the question of directors resigning over the matter which Mr Grant described as "bizarre".

The meeting was told that director Barbara Gibson would retire on December 31, 2008 and Mr Grant said he would retire during 2009.

Mr Grant said that with hindsight it would have been preferable to accept the $75 million and the legal case was "a learning experience" for the board.

In the discussion of the grant of up to 976,300 free options at nil exercise cost to Mr Cook, Mr Lowenstein said the incentive scheme was inappropriate and called for the withdrawal of the motion, noting that his group controlled about 20 million shares.

Mr Cook was unable to comment on the issue, but the same incentive plan applies to all Biota staff, not just senior management.

In his address, Mr Cook said that apart from the share price, the research and development work conducted by Biota was on schedule with significant project advances.

He said the company had $60.2 million in cash at June 30, 2008, had received $US3.5 million from Astrazeneca to broaden the geographic licence for its respiratory syncytial virus program, had completed the phase II trial of CS-8958 a long acting neuraminidase inhibitor with Daiichi-Sankyo and commenced a phase IIa human rhinovirus trial.

Mr Cook said the OIA influenza diagnostics business generated "just under $300,000 in 2008 but [the company] is not expecting any royalties beyond this financial year" and the project would lapse.

Shareholders in the room and an overwhelming number of proxy votes approved the reelection of directors Paul Bell and Grant Latta.

Two changes to the constitution and the remuneration report were approved.

Shareholders in the room supported the election of Dr Montalto, as did 5,979,238 proxy votes, with 23,922,213 proxies against. A poll showed Dr Montalto failed in his bid.

Two resolutions on Mr Cook's options were rejected by the meeting with more than 24.4 million proxy votes in favor and more than 4.5 million against.

A poll of votes was passed by about 50 million votes in favor and 30 million against.

Biota climbed two cents or 6.25 percent to 34 cents.

CORRECTION: VENTRACOR

Monday's Bioguide on Ventracor said that Thoratec's Heartmate II pump was inserted above the diaphragm. This reference should have been to Jarvik Heart's Jarvik 2000. The Heartmate II pump is inserted below the diaphragm.

ADVANCED SURGICAL DESIGN & MANUFACTURE

Advanced Surgical says the first clinical case outside Australia using its Peripheral Access Device "has successfully demonstrated the effectiveness of the treatment".

The company said the case was performed in Frankfurt last week by Prof Thomas Schmitz-Rixen, a leading investigator in the field of neo-vascularisation.

Advanced Surgical's chief executive officer Dr Greg Roger told Biotech Daily that the use of the large bore device to increase circulation went through a local approval process in Germany

Prior to commencement of treatment, the patient had already lost part of his foot to peripheral vascular disease.

Following the Peripheral Access Device (PAD) hyperfusion, "limb circulation is presently improving as expected" the company said.

Advanced Surgical said the device was presented at the inaugural Interdisciplinary Leg Summit in London October 25 and 26, 2008, at Imperial College.

The conference was dedicated to the reduction of the amount of leg amputations being performed worldwide and attended by leading surgeons and researchers in this field.

Advanced Surgical said it "featured prominently, with a stand demonstrating the Peripheral Access Device technology and the hyperperfusion treatment".

"Interest in the PAD was very strong and [Advanced Surgical] fielded enquiries from surgeons from the UK and across Europe," the company said.

Advanced Surgical said trials of the device were continuing in Australian and had begun at overseas centres.

Recently, the PAD was also presented in the on-line edition of the prestigious Journal of Vascular Surgery with inventor Dr Rod Lane the lead author.

Advanced Surgical said it was expecting the trials would "provide convincing clinical evidence of the efficacy of the device" and the company was preparing to progressively commercialize the device across the world.

Advanced Surgical said it was "on course in its plan to roll out the PAD technology through selected centres of excellence in each country".

Advanced Surgical was unchanged at 35 cents.

AGENIX

Agenix says it will take up to two months to resolve legal, financial and operational matters relating to its acquisition of the Shanghai pharmaceutical company and resume trading.

Agenix said the Australian Securities and Investments Commission had granted an extension to hold its annual general meeting until December 23, 2008.

In August the company said it expected it would require up to two months to resolve the China acquisition issues (see Biotech Daily; August 29, 2008) and subsequent to that announcement began proceedings in the Supreme Court of Victoria against former chief executive officer and chief financial officer Neil Leggett (see Biotech Daily; September 12, 15 and 16, 2008).

Agenix is in a suspension and last traded at 1.7 cents.

HEALTHLINX

Healthlinx and ARL Pathology have launched Ovplex "as the world's first early stage diagnostic test for ovarian cancer".

Healthlinx managing director Nick Gatsios said the formal launch of his company's test was "a medical milestone in women's health".

"It changes Healthlinx into a diagnostic developer and product sales company," Mr Gatsios said. "Most importantly, we believe this test could lead to many hundreds of lives being saved in Australia."

Healthlinx said the test costing $200 per test would be available through general practitioners in Melbourne before being rolled out to other states.

The company said 1500 Australian women were diagnosed with ovarian cancer each year and more than 800 of those women would die from the disease. Worldwide 230,000 cases are diagnosed annually with more than 142,000 disease fatalities.

Healthlinx chairman Prof Greg Rice said the reason ovarian cancer was the most lethal of the reproductive tract cancers was that 75 percent of women with ovarian cancer were not diagnosed until late stage disease.

"Their chances of surviving five years are probably only 20-30 percent," Prof Rice said.

"If the disease is diagnosed at early stage, when it is contained within the ovaries, the chance of surviving five years rises to 80 percent," Prof Rice said.

"That is why it is so important to try [to] develop better tests for diagnosing ovarian cancer, particularly early stage disease," Prof Rice said.

Healthlinx said it was continuing research and development to improve accuracy sufficiently to develop the world's first community-based screening test.

Healthlinx climbed 0.6 cents or 11.76 percent to 5.7 cents.

PATRYS

Patrys says it will acquire "all of the technology assets" of the US-based, Acceptys Inc, including a pipeline of natural antibodies for infectious disease indications.

Patrys said the assets include natural human antibodies directed at hepatitis C, staphylococcus A and malaria, all significant unmet medical needs with commercial potential.

The company said Acceptys had agreed to cease all research activities in the antibody field, meaning that Acceptys' exclusive rights to the Patrys natural human antibody platform for infectious disease applications, licenced to Acceptys in 2007, will terminate.

As it will no longer conduct research operations, Acceptys has agreed to transfer $US2 million to Patrys, representing nearly all of Acceptys' cash reserves.

In return for gaining ownership of Acceptys' technology and monetary assets, Patrys has agreed to issue Acceptys 11,300,000 ordinary shares or 6.9 percent of the outstanding shares of the company, holding the shares under a 12-month escrow agreement.

Acceptys will release Patrys from ongoing milestone and royalty payments otherwise due that were transferred by Acceptys to Patrys in January 2007 and Patrys will forgo its 30 percent equity interest in Acceptys.

Patrys chief executive officer Dan Devine said his company had been able to expand its asset base "through the addition of antibody programs aimed at infectious disease indications and gain complete control over our natural antibody platform".

"This transaction immediately enhances the value of both internal development and partnering opportunities," Mr Devine said.

The agreement is subject to shareholder approval at a November 28, 2008 meeting.

Patrys was unchanged at 10 cents.

ROCKEBY BIOMED

Rockeby says it has been awarded two grants worth $S750,000 ($A772,000) the Singapore's Standards, Productivity and Innovation Board.

Rockeby said the grants were awarded under the Technology Enterprise Commercialization Scheme with $S250,000 for a proof-of-concept development of a magnetic detection platform for influenza A, including avian influenza.

The second grant of $S500,000 is for a "proof-of-value" to scale up production of a rapid and sensitive test incorporating fluorescence technology for the field diagnosis of influenza A, including avian influenza.

The proof-of-concept project is planned to take one year and the proof-of-value project is planned to take two years.

Rockeby said the platform could be expanded to other infectious disease tests such as chlamydia, Dengue fever as well as hand, foot and mouth disease.

Rockeby was unchanged at 0.2 cents.

HEARTWARE

Heartware says it expects court orders approving its schemes of arrangements tomorrow with a suspension of trading as HTW on Friday October 31, 2008.

Trading of the company's Chess Depository Instruments (CDIs) will begin on Monday November 3, 2008 under the code HIN.

November 7 is the record date for the schemes and normal settlement basis begins on November 17, 2008.

Heartware fell 4.5 cents or 8.26 percent to 50 cents.