Biotech Daily

Thursday July 30, 2009

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: NOVOGEN UP 20%, LIVING CELL DOWN 16%**

*** US FTC CHALLENGES THORATEC'S HEARTWARE ACQUISITION**

*** PRIMA APPLIES FOR US PHASE IIb CVAC OVARIAN CANCER TRIAL**

*** HEALTHLINX UP 280% ON CE MARK FOR OVARIAN CANCER TEST**

*** ONDEK'S PROF BARRY MARSHALL WANTS $10m FOR H PYLORI VACCINE**

*** LIVING CELL PLACEMENT RAISES $4.2m**

*** PSIVIDA: SHARE PRICE UP ON TRIAL SPECULATION, NASDAQ PRESSURE**

*** CELL SIGNALS TAKES 16% OF MEDICAL THERAPIES FOR MIDKINE IP**

*** CIRCADIAN RELEASES 2.6m ESCROW SHARES**

*** NOVOGEN DIRECTOR PETER SIMPSON RETIRES**

*** NEURODISCOVERY FOUNDING DIRECTOR JOHN HANNAFORD RESIGNS**

*** CORRECTION: DIA-B, PALLANE**

MARKET REPORT

The Australian stock market climbed 1.15 percent on Thursday July 30, 2009 with the S&P ASX 200 up 47.6 points to 4,190.4 points. Sixteen of the Biotech Daily Top 40 stocks were up, seven fell, seven traded unchanged and 10 were untraded. All three Big Caps were up.

Novogen was best, up 13 cents or 20 percent to 78 cents with 74,144 shares traded, followed by Impedimed up 19 percent to 59.5 cents. Mesoblast, Prana and Psivida climbed more than eight percent; Genetic Technologies, Peplin and Tissue Therapies were up five percent or more; Alchemia, Cellestis and Clinuvel were up more than four percent; CSL was up two percent; with Chemgenex, Cochlear, Nanosonics and Resmed up more than one percent.

Living Cell led the falls, down 3.5 cents or 16.3 percent to 18 cents with 1.2 million shares traded, followed by Heartware down 15.6 percent to 65 cents. Avexa lost 4.2 percent; Phosphagenics was down 3.7 percent; Universal Biosensors shed 2.3 percent; with Biota down 1.8 percent.

HEARTWARE

Heartware says the US Federal Trade Commission will file a complaint in the US Federal District Court to challenge Thoratec's proposed acquisition of Heartware International.
A media release to the ASX said Thoratec and Heartware were “disappointed with the FTC's decision to challenge the acquisition”.
Heartware said the companies intended to review the FTC's decision and mutually assess the appropriate next steps and inform the market once a decision was made.
In February, Thoratec Corp said it would acquire Heartware for $US282 million ($A429 million) paying half in cash and half in Thoratec common stock (BD: Feb 12, 2009).
Heartware said at the time the purchase reflected a price of $A1.32 per Heartware Chess Depositary Instrument which traded on February 12, 2009 at 66.5 cents.
Heartware’s chief executive officer Doug Godshall told Biotech Daily that if the FTC was successful in securing a preliminary injunction against the merger the only remedy would involve litigation against the US regulator.
“We always knew it was a risk that the deal could be turned over,” Mr Godshall said.
“But shareholders are better off that the offer has been made than had it not,” he said.
Mr Godshall said that no part of the $US28 million convertible note offered by Thoratec had been drawn down and $US20 million was still available.
He said the final tranche of $US8 million would not be available until October 31, 2009 and then only if the deal was going ahead.
Heartware fell 12 cents or 15.6 percent to 65 cents with 1.2 million shares traded.

PRIMA BIOMED

Prima says it has submitted its investigational new drug application to the US Food and Drug Administration for a phase IIb trial of CVac for ovarian cancer.
The company said the submission was a major milestone in the commercialization process and “one of the critical requirements of the product’s development cycle”.
Prima said the application was “the culmination of years of scientific and pre-clinical validation of the technology and commitment from Prima and its world class medical advisory team”.
Prima said CVac was administered post-surgery and post-chemotherapy to delay relapse and control metastases.
The company said there was a large un-met medical need for new treatments for ovarian cancer which has a very high morbidity rate and there were no maintenance-based therapy products commercially available.
Prima said the protocol design for the selection of patients for the trial had been undertaken and completed, by the Fred Hutchinson Cancer Centre’s gynaecological oncologist Dr Heidi Gray in Seattle.
Prima said the Centre would host the US section of the pivotal trial with other trial centres at Melbourne’s Austin Hospital as well as hospitals attached to UCLA, Stanford, Sloan-Kettering Cancer Centre and Pennsylvania State University.
Prima executive director Martin Rogers told Biotech Daily that the FDA would review the application for up to 30 days and the company was preparing its technology transfer to the US and hoping to begin the trial by the end of 2009.
Prima fell 0.3 cents or four percent to 7.2 cents with 21.98 million shares traded.

HEALTHLINX

Healthlinx jumped as much as 280 percent to 9.5 cents on news that it has Conformitée Européenne (CE) approval for its Ovplex ovarian cancer diagnostic test.

The company said sales to the UK and the Republic of Ireland would begin immediately through Intus Healthcare and was the first time Ovplex would be available commercially outside Australia.

Healthlinx said Ovplex was "the world's first and most accurate commercially-available early stage ovarian cancer diagnostic test for symptomatic women with a 92 per cent diagnostic efficiency".

The company said the diagnostic was based on a blood test that women can request from their doctors using five protein biomarkers.

Healthlinx managing director Nick Gatsios said European approval was "substantial commercial progress for Healthlinx".

"Given the profound advantages of early detection of ovarian cancer, Ovplex may save many thousands of lives," Mr Gatsios said.

Healthlinx said more than 240,000 new cases of ovarian cancer were diagnosed each year with more than 130,000 women dying from the disease worldwide each year.

Healthlinx closed up 5.9 cents or 236 percent to 8.4 cents with 4.4 million shares traded.

ONDEK

Nobel prize-winning scientist Prof Barry Marshall wants to raise $10 million to take Ondek's Helicobacter pylori-based anti-influenza virus to formal clinical trials.

Prof Marshall told Biotech Daily that it was possible to take part of the influenza virus DNA and attach it to a benign strain of Helicobacter pylori providing an oral route for vaccination.

In 2005 Prof Marshall won his Nobel Prize for Medicine and Physiology with Prof Robin Warren for discovering Helicobacter pylori and its causal connection to most stomach ulcers.

On its website, Ondek describes the technique as the "Helicobacter pylori platform technology" or HPPT.

Prof Marshall said that there were billions of strains of Helicobacter pylori and Ondek had selected fewer than 20 strains for further investigation of which one would be chosen as the carrier for the vaccine.

He said there was preliminary data on about 40 volunteers in Germany and the US.

He said that most people carried the bacteria but 90 percent were asymptomatic and most did not develop ulcers.

Prof Marshall said that once the company attached the part of the influenza virus to the bacteria it would be a genetically modified organism requiring regulatory approvals.

Prof Marshall said Ondek had already solved the technical problems of genetically modifying the bacteria and was searching for the most benign strain.

He said preclinical trials were underway in mice, "but it is a human bug" so he expected the results in humans to be better than in mice.

He said that efficacy could be confirmed by influenza antibody levels in blood.

Prof Marshall said he wanted to keep Ondek as an unlisted company until it reached significant milestones and then would consider listing.

He said Ondek's cash burn was about $2 million a year and had funds to the middle of 2010.

Prof Marshall said he wanted to raise $10 million to fund the company beyond phase I clinical trials which he hoped to begin by the end of 2010.

LIVING CELL TECHNOLOGIES

Living Cell Technologies has raised $4.2 million through the issue of 25.5 million shares at 16.5 cents a share.
The company will provide two options for every five new shares, exercisable at 24 cents until December 31, 2010.
Living Cell fell 3.5 cents or 16.3 percent to 18 cents with 1.2 million shares traded.

PSIVIDA

Psivida says upward pressure on its share price has come from Nasdaq trading ahead of expected positive results from its phase III diabetic macular oedema trial.
Psivida's investor relations director Brian Leedman told Biotech Daily that the reason the Australian share price was up 16.1 percent yesterday and 17.2 percent the day before on low volumes was that there had been greater share trading on the US Nasdaq.
Mr Leedman said Psivida closed at $US2.34 on July 28, 2009 with 59,357 shares traded and at $US2.30 on July 29, 2009 with 61,332 shares traded.
He said each Nasdaq PSDV share was equivalent to an Australian PVA share.
Mr Leedman said the 1,000 patient phase III trial of Iluvien (formerly known as Medidur) for diabetic macular oedema was expected to be completed by October 2009 with results by the end of the year.
If approved, he said it would be the first US Food and Drug Administration approved drug for diabetic macular oedema.
Mr Leedmand said he expected approval would be in line with the six months it took for Vitrasert and Retisert, two drugs approved for the company's former US subsidiary Control Delivery Systems, now part of Psivida.
Psivida was up 20 cents or 8.2 percent to $2.65.

MEDICAL THERAPIES

The Yokohama-based Cell Signals Inc has been issued a further 15 million shares as the final payment for the company's Midkine intellectual property assets.
Cell Signals' substantial shareholding in Medical Therapies has increased from 20,000,000 shares (15.26%) to 35,000,000 shares (16.46%).
Separately, Medical Therapies said that although it had less than one quarters cash according to its Appendix 4C quarterly report, it had raised $550,221 after June 30, 2009.
Medical Therapies said it had a net operating cash burn of $251,000 in the three months to June 30, 2009, with cash of $157,000.
Medical Therapies was unchanged at 2.8 cents.

CIRCADIAN TECHNOLOGIES

Circadian says it will release 2,558,714 shares from escrow on August 14, 2009.
Circadian said the shares were owned by the Ludwig Institute for Cancer Research and Licentia Limited the commercial arm of the University of Helsinki and were part-payment for Circadian's acquisition of Vegenics (BD: Jul 15, Aug 14, 2008).
The company said a further 2,558,716 shares were due to be released from escrow on August 14, 2010.
Circadian has a total share issue of 45,241,928 shares including the restricted securities.
Circadian was up half a cent or 0.66 percent to 76 cents.

NOVOGEN

Novogen says that director Peter Simpson has resigned as a director.
The company made no mention of a replacement director.
Novogen was up 13 cents or 20 percent to 78 cents.

NEURODISCOVERY

Neurodiscovery says founding director John Hannaford has resigned "as part of the company's restructuring and focus on cost minimization".
Neurodiscovery was untraded at 3.6 cents.

CORRECTION DIA-B, PALLANE

Last night's edition quoted ASX data provided by Commonwealth Securities saying Dia-B last traded at 28 cents. In fact the company last traded at 1.4 cents, prior to a consolidation in preparation for the merger with Pallane.
No sub-editors were hurt in making this correction.