Biotech Daily

Friday July 23, 2010

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: IMPEDIMED UP 14%; LBT DOWN 12%**

*** SIRTEX TRIALS SIR-SPHERES FOR KIDNEY CANCER**

*** BIOTRON SAYS BIT225 EFFECTIVE AGAINST HIV IN DENDRITIC CELLS**

*** PRIMA ENROLS FIRST PHASE IIb OVARIAN CANCER VACCINE PATIENT**

*** AVEXA TAKES ON CALZADA; BACKS APRICITABINE**

*** ACUVAX CONFIRMS MERCK ACQUISITION OF HAWAII BIOTECH**

*** 'ANESTHESIOLOGY' BACKS BPH'S CORTICAL DYNAMICS ALGORITHM**

*** CATHRX PARTNER ACQUIRES CATHETER REPROCESSOR**

*** NASDAQ GIVES NOVOGEN 180 DAYS TO CLIMB ABOVE $US1**

*** PRIMA REAPPOINTS CEO MARTIN ROGERS DIRECTOR, DR NEIL FRAZER**

MARKET REPORT

The Australian stock market climbed 1.91 percent on Friday July 23, 2010 with the S&P ASX 200 up 83.7 points to 4458.4 points.

Sixteen of the Biotech Daily Top 40 stocks were up, nine fell, seven traded unchanged and eight were untraded. All three Big Caps were up.

Impedimed was best, up nine cents or 13.85 percent to 74 cents with 54,411 shares traded.

Compumedics and Virax climbed more than seven percent; Acrux, Living Cell, Prima and Tissue Therapies were up five percent or more; Sirtex was up four percent; Novogen was up 3.85 percent; CSL and Viralytics rose more than two percent; with Biota, Nanosonics and Optiscan up more than one percent.

LBT led the falls, down 0.9 cents or 12.3 percent to 6.4 cents with 110,633 shares traded, followed by Antisense down 5.6 percent to 1.7 cents with 1.3 million shares traded.

Chemgenex and Patrys fell more than four percent; while Alchemia, QRX and Psivida shed two percent or more.

SIRTEX MEDICAL

Sirtex Medical says it will assess the safety and tolerability of its SIR-Spheres targeted internal radiation therapy for inoperable primary kidney cancer.

Sirtex said SIR-Spheres had been used to treat inoperable liver cancers and this would be "the first time … the therapy has been used to treat cancer tumors outside the liver".

The 24-patient study called Resirt will be conducted at Sydney's St George and Westmead private hospitals with recruitment due to begin in August, 2010.

Sirtex chief executive officer Gilman Wong said that investment in the study was "part of our long term plan to significantly expand our business by realizing the full potential of SIR-Spheres microspheres".

"Evidence from studies like this will help broaden the clinical use of SIR-Spheres microspheres and potentially provide a useful new therapy for patients with few effective options," Mr Wong said.

Sirtex's lead investigator for the study Dr Paul de Souza said selective internal radiation therapy worked well in treating many different forms of liver cancer.

"We hope this trial will tell us if it is feasible and safe and can help improve the outcomes for patients with a type of kidney cancer known as renal cell carcinoma that is not suitable for treatment by surgery or other conventional techniques," Dr de Souza said.

Sirtex said that in 2009, about 2,500 Australians and 60,000 Americans were diagnosed with kidney cancer.

The company said that surgery was the main treatment for earlier stages of kidney cancer and advanced kidney cancer carried a poor prognosis.

Study approval followed a successful Sirtex-sponsored preclinical study in pigs completed by Edinburgh's Western General Hospital department of urology led by Dr Simon Mackie.

The preclinical study showed that the delivery of targeted radiotherapy to the kidney using SIR-Spheres microspheres was feasible and safe, warranting further evaluation as a potential treatment for localized disease in patients who are unfit for surgery.

Sirtex was up 20 cents or four percent to $5.15.

BIOTRON

Biotron says its lead drug BIT225 has the potential to prevent the establishment of HIV infection in the first cells to encounter the virus at the point of infection.

Biotron said its senior virologist Dr John Wilkinson presented in vitro data showing BIT225's efficacy at the International AIDS Conference in Vienna, this week.

The company said dendritic cells acted like the watch dogs of the immune system and reached the virus first when the body was infected.

The company said that within about 24 hours of first infection, HIV started replicating in the dendritic cells and was then transmitted to the body's T cells, where the virus established a more explosive infection.

Biotron said that BIT225 was able to significantly reduce levels of HIV in dendritic cells in the laboratory, with up to 89 percent reduction in virus transferred to uninfected T cells.

The company said the results were significant "as prevention or minimization of the establishment of HIV infection would potentially ameliorate the devastating effects of HIV infection in the body" and the finding opened up "a new avenue for potential exploitation of BIT225, in addition to its potential use in controlling viral reservoirs in patients with established infection".

Biotron said it was progressing protocols for a phase Ib/IIa trial of BIT225 in HIV patients in addition to the proposed BIT225 hepatitis C phase II trial.

Biotron was untraded at 7.5 cents.

PRIMA BIOMED

Prima says it has enrolled the first of 60 patients in its randomized, open-label, phase IIb trial of its ovarian cancer vaccine Cvac.

Prima said that the trial would evaluate the safety and efficacy of CVac as a single agent for epithelial ovarian cancer patients who are in clinical complete remission following first or second-line chemotherapy at sites including the Fred Hutchinson Cancer Center in Seattle Washington and the Peter MacCallum Cancer Center in Melbourne.

Prima said recruitment would be completed by first quarter April 2011.

In 2007 Prima said its full phase IIa clinical trial results showed statistically significant ovarian cancer reduction but the company needed to raise $10 million for a pivotal trial, which it hoped to hold that year (BD: Mar 14, 2007), but the funds were never raised.

At that time Prima said it exceeded its primary objective of reducing or stabilizing the blood marker for cancer CA125 in at least 15 percent of patients.

With four of 21 patients (19 percent) showing such a response, Prima said its Cvac treatment had exceeded expectations.

The 2007 trial showed that in terms of disease progression-free survival and safety, Prima said two patients, whose life expectancy was about six months at the start of the trial, continued receiving Cvac treatment after the trial concluded.

Today, Prima's chief operating officer Matt Lehman told Biotech Daily that the primary endpoint was progression-free survival and the first patient was expected to be dosed by the end of July, with recruitment completed by July 2011 and results by the end of 2012.

Mr Lehman said patients would be dosed in four-weekly cycles for seven cycles and then less frequently for a total period of 48 weeks.

Prima said that to assess progression-free survival, clinical assessments would be performed every four weeks and imaging with computed tomography or magnetic resonance imaging would be performed every 12 weeks, until progression or withdrawal of the patient from trial.

The company said initial safety data was expected by the end 2011, after completion of the treatment phase.

Prima said the trial would augment promising efficacy data generated by previous studies, including the phase IIa pilot study completed in 2007 on 28 patients.

Prima chief medical officer Dr Neil Frazer said CVac was "an immunotherapy that utilizes the body's own immune system to fight cancer, with far fewer side effects than traditional oncology treatments".

"Unfortunately, even with advances in ovarian cancer therapy, a large percentage of women who are successfully treated initially will relapse," Dr Frazer said.

"Currently, no therapy has demonstrated survival benefit for ovarian cancer patients in remission," Dr Frazer said.

Prima said the first six subjects would be treated with CVac in an open-label fashion to confirm the consistency of manufacturing of the vaccine and its safety when given to ovarian cancer subjects who are in first or second clinical complete remission.

The company said that once manufacturing characteristics were confirmed as consistent and the initial cohort completed three injections of vaccine without treatment-related adverse events, enrollment into the randomized, controlled study would proceed.

The company said 54 subjects across six or more global clinical sites would be randomized to CVac or standard-of-care after having achieved a clinical complete remission.

Performance status and adverse events would be assessed at each clinical assessment until disease progression.

Prima was up half a cent or five percent to 10.5 cents.

AVEXA

Avexa has described its rational for continuing with apricitabine despite an impending independent review and has restated its opposition to Calzada's request for a board seat.
In a 'Quarterly news report to shareholders' chairman Joe Baini said the company would "shortly initiate an independent review" of Avexa's assets, including but not limited to apricitabine or ATC and the $23 million cash reserves.
Mr Baini said despite its 16 percent holding Calzada had been declined board representation.
"Calzada acquired its Avexa shares following announcement by the previous board that it was ceasing the ATC program and the subsequent sharp decline in the Avexa share price," Mr Baini said.
"Calzada has indicated that it may write directly to Avexa shareholders in the near future, and the board respects its right to do so," Mr Baini said.
"Calzada has sent a series of correspondence to Avexa and its directors over the past two weeks, occupying substantial time and financial resources," Mr Baini said.
He said the conflict "does not distract the company from its current strategy".
In a section entitled 'Revisiting ATC: A Rationale for Review' Avexa said apricitabine or ATC was "Avexa's most clinically advanced, and therefore potentially, the company's most important asset".
The failure of the company to find a partner and non-significant phase III trial results led to a share price crash and the removal of the previous board by supporters of the present board (BD: May 10, 26; Jul 26, 2010).
Avexa said today that "although there have been setbacks in the program, ATC has many positive features which provide a rationale to further investigate the commercial potential of this drug".
The company listed a series of treatment advantages of the drug and said it was for those reasons there was support from patient organizations to continue development of ATC.
Avexa said that, in parallel with the independent review, its first step would be to meet with the major regulatory authorities to discuss a new clinical trial design, to determine the shortest and least risky route to approval.
The trial strategy would be designed to reduce the risk of failure, better demonstrate the differences between ATC and the existing treatment 3TC, and demonstrate the efficacy of the drug in a manner that is suitable for regulatory approval.
Avexa was unchanged at 3.1 cents with 1.8 million shares traded.

ACUVAX, MERCK SHARP & DOHME, HAWAII BIOTECH

Acuvax told the ASX today that Merck Sharp & Dohme's $US3.1 million ($A3.5 million) bid for Hawaii Biotech's assets has been approved by the US bankruptcy courts.
Acuvax said that while the terms of the deal were yet to be finalized, "it has been reported that Merck Sharp & Dohme will pay $US3.1 million" (BD: Jul 22, 2010).
At this price, it is unlikely that the sale will generate sufficient funds for a return to Hawaii Biotech shareholders, Acuvax said.
Acuvax holds about 26 percent of Hawaii Biotech.
Acuvax was untraded at 0.3 cents.

BPH CORPORATE, CORTICAL DYNAMICS

BPH says its 3.6 percent subsidiary Cortical Dynamics' brain activity monitor has been supported in an editorial in the August edition of 'Anesthesiology'.

A paper entitled 'Propofol and Remifentanil Differentially Modulate Frontal Electroencephalographic Activity' to be published in the August edition of 'Anesthesiology' reports on 45 patients undergoing surgery, in which the physiologically motivated fixed order time series modelling of electroencephalographic activity was able to differentiate the effects of the hypnotic propofol from the analgesic remifentanil.

The paper, authored by Swinburne University of Technology's Prof David Liley, Nicholas Sinclair, Tarmo Lipping, Bjorn Heyse, Hugo Vereecke and Michel Struys said the approach might enable independent monitoring of a patient's level of consciousness and analgesic state.

An abstract is at: http://www.ncbi.nlm.nih.gov/pubmed/20613470?dopt=Abstractplus.

BPH said an accompanying independent editorial entitled 'Disentangling Hypnos from His Poppies' by Dr Jamie Sleigh said "a clear scientific understanding of the causal mechanistic links among drug effect and electroencephalographic and neurobiologic function must be superior to the existing heuristically derived black-box electroencephalographic monitors".

BPH chairman David Breeze told Biotech Daily: "This is the most important validation of the Cortical Dynamics technology ever published."

"This study validates the technology, an algorithm of brain activity during anaesthesia and critically sets out the differentiation of brain states," Mr Breeze said.

BPH said that in its editorial decision, the journal said the work was "an interesting and novel approach to analyzing the electroencephalographic effects of anesthetic and opioid drugs".

"The effect of opioids on the EEG is highly relevant to neuromonitoring in anesthesia, and will be important for the development of new clinically useful monitors," BPH quoted the editorial decision.

Prof Liley said the technology had the potential for other diagnostic applications that could improve the understanding of mental illnesses, stroke, psychosis and Alzheimer's disease.

BPH was unchanged at 11.5 cents with 4.4 million shares traded.

CATHRX

Cathrx says its partner Pioneer Medical Devices has acquired Ascamed GmbH a specialized re-processor of electrophysiology catheters.

Cathrx recently announced that it would change its strategy so that is cardiac catheters could be reprocessed for reuse (BD: Mar 5, 2010).

Cathrx chief executive officer Jeff Goodman said that the acquisition underlined Pioneer's "commitment to the success of its marketing effort in Europe and is a strong validation of our decision to partner with them in this region".

Mr Goodman said partnering with Pioneer was the first step to sell the re-useable devices via reprocessing channels.

"Cathrx [electrophysiology] catheters, which are designed and purpose built for re-use, have the potential to penetrate the market for single use devices," Mr Goodman said.

Pioneer chief executive officer Robert Schrödel said that through "the combined forces of our specialized reprocessing companies Redis GmbH and Ascamed, the Pioneer group of companies is rapidly emerging as a high-performance manufacturer and re-processor of complex medical devices".

Cathrx was unchanged at 20 cents.

NOVOGEN

Novogen says it is on a 180 day Nasday notice to comply with its share bid price being higher than $US1.00 ($A1.12).

Novogen said the July 19, 2010 Nasdaq letter said that for the last 30 consecutive business days the bid price of the company's common stock closed below the minimum $US1.00 per share requirement for continued inclusion on the Nasdaq market.

Novogen said the Nasdaq gave it "a grace period of 180 calendar days, or until January, 18, 2011, to regain compliance".

The company said that to regain compliance, shares of its common stock must maintain a minimum bid closing price of at least $US1.00 per share for a minimum of 10 consecutive business days during the grace period.

Novogen said an American Depository Receipt (ADR) represented five ASX shares, so the bid price of an ADR on the Nasdaq was five times the ASX share bid price.

The company said it would "actively monitor the bid price of its common stock between now and January 18, 2011".

Novogen had 102,125,894 shares on offer on May 31, 2010, which included 10,025,830 ADRs equivalent to 49.1 percent of the company.

Novogen was up half a cent or 3.85 percent to 13.5 cents.

PRIMA BIOMED

Prima says it has reinstated chief executive officer Martin Rogers as a director, following his departure from the board last month (BD: Jun 25, 2010).

Mr Rogers told Biotech Daily that he thought at the time its was a good idea to step down from the board to focus better on the company's activities but shareholders had advised him that they wanted him back on the board.

It is usual for chief executive officers to be members of their company's boards.

Prima said chief medical officer Dr Neil Frazer has been appointed as an executive director.

The company said that non-executive director Albert Wong was appointed as interim chairman.

Prima said it was negotiating with an external candidate for the role of chairman.

Prima said the US-based Dr Frazer was appointed chief medical officer in November 2009 and was playing "a key role in overseeing the CVac ovarian cancer treatment vaccine trials.

The company said Dr Frazer had more than 23 years experience in the pharmaceutical industry, including 10 years experience in oncology drug development and had a strong depth of expertise in managing the clinical development process of new drug applications.

Prima said Dr Frazer had been involved in the successful applications for 10 new chemical entities in multiple therapeutic areas, plus more than 20 applications for line extensions of pharmaceutical drug applications.

Dr Frazer has a Bachelor of Medicine and Bachelor of Surgery from the University of Edinburgh, a Fellowship from the Royal College of Anaesthetists in London and a Fellowship in Pharmaceutical Medicine from the Royal College of Physicians.