Biotech Daily

Monday March 23, 2015

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: COMPUMEDICS UP 13%, PATRYS DOWN 18%**

*** OSPREY PLACEMENT RAISES $16m**

*** INVION: 'FDA APPROVES INV102 TRIAL STRATEGY'**

*** STARPHARMA DENDRIMER-DOCETAXEL TRIAL '50% RECRUITED'**

*** BPH EGM FOR DIRECTOR SHARES, OPTIONS**

MARKET REPORT

The Australian stock market fell 0.32 percent on Monday March 23, 2015 with the S&P ASX 200 down 19.4 points to 5,956.1 points.

Nineteen of the Biotech Daily Top 40 stocks were up, nine fell, 11 traded unchanged and one was untraded. All three Big Caps fell.

Compumedics was the best, up 1.5 cents or 13.0 percent to 13 cents with 22,500 shares traded, followed by Phosphagenics up 8.3 percent to 3.9 cents with 30.0 million shares traded.

Living Cell and Osprey climbed more than seven percent; Medical Developments was up 6.8 percent; Nanosonics and Starpharma rose more than four percent; Biotron, GI Dynamics, Optiscan, Prima and Universal Biosensors were up more than three percent; Atcor, Bionomics, Oncosil and Tissue Therapies rose more than two percent; Viralytics was up 1.1 percent; with Acrux and Impedimed up by less than one percent.

Patrys led the falls, down 0.2 cents or 18.2 percent to 0.9 cents, with 70,000 shares traded, followed by Genetic Technologies down 10.8 percent to 3.3 cents with 3.3 million shares traded.

Uscom lost 9.1 percent; Cellmid fell four percent; Psivida and Sirtex were down more than three percent; Clinuvel and Mesoblast shed more than two percent; with Anteo, Cochlear, CSL and Resmed down more than one percent.

OSPREY MEDICAL

Osprey says its “heavily oversubscribed” placement has commitments for 30,800,000 CHESS depositary interests (CDIs) at 53 cents each to raise $16,324,000.
Osprey said the CDI were equivalent to 15,400,000 US shares.
The company said that the funds strengthened its balance sheet as it pursued its primary objectives including completion of the Avert cardiac dye reduction system’s post market trial and US Food and Drug Administration submission for enhanced marketing claims targeted of the end of 2015, as well as establishing routine adoption of Avert in initial commercial sites in Texas and expanding commercial sales in Texas.
Osprey said that the funds would be used to prepare for a full US launch of Avert in early 2016 and for ongoing research and development.
Osprey chief executive officer Mike McCormick said that the “oversubscribed placement ... further broadens our shareholder base with strong support received from both existing institutional shareholders as well from several new institutions in both Australia and overseas”.
Osprey climbed 4.5 cents or 7.8 percent to 62.5 cents.

INVION

Invion says the US Food and Drug Administration has approved its strategy for inhaled INV102, or nadolol, and its two phase I study outlines and proposed toxicology program.
Invion said that the FDA pre-investigational new drug application meeting enabled the further development of INV102 as a potential therapy to treat chronic airway diseases like asthma and was “a critical development milestone”.
The company said that the FDA had examined and approved the strategy, as well as the associated drug delivery hardware, a pressurized metered dose inhalation technology developed by global manufacturing collaborator 3M Drug Delivery Systems.
Invion said that the meeting accepted its chemistry and manufacturing plan, which was ongoing at 3M Drug Delivery Systems and confirmed that the proposed toxicology program was necessary and sufficient as well as agreeing the targets for inhaled INV102, based on understanding the mechanism of action on the airway epithelium.
Invion chief medical officer Dr Mitchell Glass said the meeting had provided a roadmap for the development of inhaled nadolol to treat chronic inflammatory airway diseases.
“We have confirmed and clarified the path forward for the inhaled formulation of INV102 to provide lifelong treatment of chronic airway diseases,” Dr Glass said.
“This is a key development milestone,” Dr Glass said.
Invion said that the FDA was aware of the “recent positive interim data from [its] smoking cessation study of oral INV102, which provided clinical target validation for using this drug to treat the airway epithelium directly”.
“Importantly, Invion is allowed to leverage results from ongoing studies with oral nadolol to provide safety, efficacy and exposure data that will expedite inhaled nadolol development,” Dr Glass said.
Invion said that nadolol was a beta blocker, or beta adrenergic biased ligand, currently used to treat high blood pressure and migraine and the company was repurposing the drug to treat chronic inflammatory airway diseases, including asthma and chronic obstructive pulmonary disease.
The company said that recent interim data from a phase II trial of oral nadolol in smoking cessation “was highly encouraging, demonstrating the compound’s efficacy on four key biomarkers associated with lung inflammation” (BD: Jan 19, 2015).
Invion climbed 1.6 cents or 55.2 percent to 4.5 cents with 39.3 million shares traded.

STARPHARMA

Starpharma says it has recruited about 50 percent of the patients for its phase I trial of dendrimer-docetaxel for advanced cancers.

Last year, Starpharma began the 30-patient phase I dose-escalation trial of dendrimer-enhanced (DEP) docetaxel for solid tumors at the Nucleus Network facility at Melbourne's Alfred Hospital, with the primary objective to establish the maximum tolerated dose and dose limiting toxicities of dendrimer-docetaxel, dosed intravenously once every three weeks (BD: Jan 23, 2014).

The company said at that time that the secondary objective was to identify the safety, pharmacokinetic and tolerability profile of dendrimer-docetaxel in patients with advanced cancer and the key outcomes would be to define a recommended dose for future studies as well as to explore preliminary anti-tumor efficacy of the product.

Today, Starpharma said that the trial continued to show "very encouraging clinical data" with the drug well-tolerated and with no neutropenia or hair loss observed, despite continued dose escalation and some patients receiving as many as six cycles of treatment.

Starpharma chief executive officer Dr Jackie Fairley said that it was "very pleasing to see these continued strong results from the trial which are consistent with our earlier good preliminary data for DEP-docetaxel from the trial's first cycle of dosing and also the preclinical studies".

"The beneficial features from the pharmacokinetic analyses and preclinical studies include a substantially extended duration of exposure, greatly increased extent of exposure to drug and reduced peak levels of drug," Dr Fairley said.

Starpharma said that four sites were involved in the trial, with Sydney's Liverpool Hospital recently added for the completion of the dose escalation phase and in readiness for the final phase of the study which will assess the maximum tolerated dose in an expanded patient cohort.

The company said that its two double-blinded, placebo controlled phase III trials of Vivagel for the prevention of recurrence of bacterial vaginosis were progressing well, with the majority of the 100 sites recruiting.

Starpharma said that the trials were being conducted across the US, Canada, Mexico, Europe and Asia, with each trial planned to enrol around 600 women.

Starpharma was up two cents or 4.6 percent to 45.5 cents.

BPH ENERGY

BHP will vote to grant executive chairman David Breeze 11,435,832 shares, 5,000,000 options to company secretary Deborah Ambrosini and 2,000,000 options each to directors Hock Goh and Bruce Whan.

The extraordinary general meeting will be held at 14 View Street, North Perth, Western Australia on April 20, 2015 at 11am (AWST).

BPH was unchanged at 0.6 cents.