Biotech Daily

Monday May 23, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: STARPHARMA UP 10%; PRANA DOWN 19%**

*** STARPHARMA PHASE II TRIAL SELECTS 1% VIVAGEL VAGINOSIS DOSE**

*** 3M DEVELOPS PHOSPHAGENICS OXYCODONE PAIN RELIEF PATCH**

*** RESONANCE TRIAL BACKS FATTY LIVER DIAGNOSTIC**

*** PHYLOGICA EXTENDS ROCHE NEUROLOGIC DISORDERS LICENCE**

*** FDA QUESTIONS VIRALYTICS PHASE II MELANOMA TRIAL DESIGN**

*** COGSTATE $1.5m DEPRESSION CONTRACT**

*** CEPHALON CLOSING-IN ON CHEMGENEX TAKEOVER; 7% SHARES TO GO**

*** PHARMAXIS REQUESTS EU CYSTIC FIBROSIS TRADING HALT**

MARKET REPORT

The Australian stock market fell 1.88 percent on Monday May 23, 2011 with the S&P ASX 200 down 89.2 points to 4643.0 points.

Six of the Biotech Daily Top 40 stocks were up, 17 fell, eight traded unchanged and nine were untraded. All three Big Caps fell.

Starpharma was best, up 13 cents or 9.6 percent to $1.49 with 2.9 million shares traded.

QRX climbed 5.4 percent; Phosphagenics was up 3.3 percent; with Universal Biosensors up 1.7 percent.

Prana led the falls, down four cents or 19.1 percent to 17 cents with 228,000 shares traded, followed by LBT down 16 percent to 4.2 cents with 264,000 shares traded.

Antisense and Viralytics lost more than nine percent; Mesoblast fell 7.2 percent; Bioniche was down 5.4 percent; Bionomics fell 4.3 percent; Benitec, Genetic Technologies and Patrys lost more than three percent; Phylogica shed 2.9 percent; with Biota, CSL, Prima, Resmed and Sirtex more than one percent.

STARPHARMA

Starpharma says its 132-patient dose-ranging phase II trial of Vivagel for bacterial vaginosis has demonstrated efficacy of the 1% dose compared to placebo.

Starpharma said Vivagel met its primary endpoint with 1% of the active ingredient SPL7013, dosed once daily for seven days, resulting in 74 percent of patients achieving clinical cure two to five days after completion of therapy compared to 22 percent in the placebo group ($p = 0.0002$).

The company said that two to three weeks after completion of therapy, 46 percent of patients achieved clinical cure of bacterial vaginosis [BV] compared to 12 percent for the placebo ($p = 0.006$) indicating that Vivagel provided lasting cure in a significant proportion of the 33 women in that cohort.

The trial compared SPL7013 strengths of 0.5%, 1% and 3% against a placebo, with the 3% strength achieving a significant 63 percent cure at end of treatment (day nine to day 12) and a non-significant 28 percent cure result at test of cure (day 21 to day 30).

The results showed the 0.5% strength had a 55 percent cure at end of treatment with a 23 percent non-significant cure at test of cure.

Starpharma said that both 1% results “were highly statistically significant and cure at both time points [was] considered …important in the clinical management of BV”.

Starpharma chief executive officer Dr Jackie Fairley told Biotech Daily the results were as expected and it was important to do minimum harm to Lactobacilli while causing maximum harm to the pathogenic bacteria such as Gardnerella, Prevotella and Bacteroides.

“Nuking everything is not a good outcome,” Dr Fairley said.

“It can cause secondary infections such as candida,” Dr Fairley said.

Dr Fairley said bacterial vaginosis was caused by multiple kinds of bacteria and it was important to kill those strains but not “the good bacteria like Lactobacilli”.

The company said the main symptoms of bacterial vaginosis were unpleasant vaginal discharge and odor and in the study, vaginal bacterial vaginosis discharge as assessed by the investigator was cured following treatment in 89 percent of the Vivagel treated patients and unpleasant vaginal odor was cured in 78 percent of the Vivagel treated patients.

Dr Fairley said the company’s objective was to develop an efficacious product “that avoids the side-effects and other shortcomings of conventional antibiotics”.

“This phase II study was a crucial test of the product and these exciting results confirm the significant commercial potential of Vivagel for [bacterial vaginosis],” Dr Fairley said.

“We are also very encouraged by the implication of these results for the additional application of Vivagel for prevention of [bacterial vaginosis] recurrence,” Dr Fairley said.

Starpharma said that existing treatments for bacterial vaginosis, such as the antibiotics metronidazole and clindamycin, had cure rates of between 35 percent and 65 percent when assessed two to three weeks after therapy, with shortcomings in terms of side-effects or tolerability, high levels of antibiotic resistance and incompatibility with condoms.

The company said that Vivagel was well tolerated, was not absorbed, was free from systemic effects, could be used with condoms and had the potential to be used for prolonged periods to prevent recurrence.

Starpharma said adverse events were similar across all placebo gel and Vivagel groups, with no severe grade 3 adverse events observed in the Vivagel groups, but two severe adverse events in the placebo group.

The company said the results supported a new patent filing which would extend Vivagel protection to at least 2032 and it would hold discussions with regulatory authorities, with a view to starting phase III registration trials in late 2011 or early 2012.

Starpharma was up 13 cents or 9.6 percent to $1.49 with 2.9 million shares traded.

PHOSPHAGENICS

Phosphagenics says 3M Drug Delivery Systems has refined its oxycodone transdermal patch prototype and will develop an improved version for clinical trials later this year.

Last year, Phosphagenics signed a consultancy agreement with 3M Corp for the development of its oxycodone patch, but details were not disclosed (BD: Nov 16, 2011).

The company said the development of the new patch had begun at 3M's laboratory in Minnesota and the Melbourne-developed technology had "the potential to revolutionize" the delivery of the oxycodone in its tocopheryl phosphate mixture or TPM transdermal delivery technology.

Phosphagenics chief executive officer Dr Esra Ogru said the original patch prototype was effective in human trials, but the technology had been boosted by a five-fold improvement in delivering the drug through human skin during in vitro studies, resulting from the collaboration with 3M, which should improve the commercial prospects for the patch.

"Working with 3M with its expertise in patch technology and manufacturing has enabled us to refine and dramatically improve the delivery of oxycodone patch," Dr Ogru said.

"Oxycodone patch development is the core company pharmaceutical product and its commercialization is the company's number one imperative," Dr Ogru said. "It offers the best medium term value inflection potential for the company."

"While we continue demonstrating the versatility of our platform technology in [cosmetics] and dermatology products, we remain focused on our high calibre pharmaceutical agenda," Dr Ogru said.

Dr Ogru said the global market for chronic pain products was about $US6 billion a year and the oxycodone market was $US3.2 billion a year, with only for oral drugs available.

The company said completion of the scale-up stage would lead to phase II/III clinical trials scheduled to begin by the end of the year.

Phosphagenics was up half a cent or 3.3 percent to 15.5 cents with 6.1 million shares traded.

RESONANCE HEALTH

Resonance says a study of its diagnostic for the assessment of fatty liver disease shows it can accurately assess the severity of fatty liver, replacing the need for an invasive biopsy.

Resonance said the study evaluated the magnetic resonance imaging-based diagnostic with 46 subjects with non-alcoholic fatty liver disease, non-alcoholic steatohepatitis and/or hepatitis C.

Resonance said about one-third of the American population had fatty liver and non-alcoholic fatty liver disease was the most common liver disease in the US and Europe.

The company said an accurate diagnosis of early stage fatty liver disease could provide a better outcome for patients, where the condition could be addressed before the onset of organ damage.

Resonance said the test could also be used in clinical studies associated with the development of new therapies to assist in the management of non-alcoholic fatty liver disease and non-alcoholic steatohepatitis where repeat measurements of liver fat content were required.

The company said each patient underwent a liver biopsy and the degree of liver fat was scored by two independent methods and compared to the MRI-based result, showing a high level of sensitivity and specificity for the test.

Resonance said it had begun preparation of a submission to the US Food and Drug Administration to gain regulatory approval for the product.

Resonance was up 0.6 cents or 31.6 percent to 2.5 cents with 2.6 million shares traded.

PHYLOGICA

Phylogica says it has extended its collaboration with the Roche for cell-penetrating peptides derived from its Phylomer drug discovery platform.
Phylogica said the Swiss-based Roche had an option to licence a specific Phylomer peptide with demonstrated cell-penetration activity for application to delivery across the blood-brain barrier.
The company announced the neurological disorders licence with Roche last year and in February said it had achieved the first milestone (BD: Oct 21, 2010; Feb 17, 2011).
Phylogica said that in partnership with Roche, it had identified cell-penetrating Phylomer peptides, some of which have the potential to cross the blood-brain barrier and could be used to develop novel treatments for neurological diseases.
The company said the discovery of biological drugs that could target neuronal cells had been a challenge for the pharmaceutical industry.
Phylogica fell 0.2 cents or 2.9 percent to 6.6 cents.

VIRALYTICS

Viralytics says the US Food and Drug Administration has required clarification of two issues before allowing its phase II trial of Cavatak for melanoma.
Viralytics said the FDA advised that the clinical hold for investigational new drug application phase II trial would remain in place until the issues were resolved.
The company said the two items related to the technical definition of efficacy measurements to be used in the proposed trial and the timing of independent patient safety review.
Viralytics said it would accept the FDA's suggestions on these two items and lodge a clinical hold full response within the next five days.
The company said the FDA had up to 30 days from the date of lodgment of the reply to either remove the clinical hold or write with further questions.
Viralytics said the removal of the clinical hold would allow it to proceed immediately with the planned phase II intra-tumoral 54 patient melanoma trial.
Viralytics fell 0.9 cents or 9.3 percent to 8.8 cents with 23.3 million shares traded.

COGSTATE

Cogstate says it has signed a $US1.55 million ($A1.47 million) contract with an unnamed pharmaceutical company for a phase II trial of a treatment for depression.
Cogstate said it would provide its cognitive testing technology and associated services to 800 patients located in 100 sites around the world, with the computerized cognition testing software and associated on-line site training materials, provided in 11 languages.
The company said that cognition, as measured by the tests would be an exploratory efficacy endpoint in the study.
Cogstate said the study would investigate dose dependent effects of the study compound on cognitive function to determine whether improvements are superior to continuation of existing medication.
Cogstate was untraded at 20 cents.

CHEMGENEX

Cephalon says it has increased acceptances for its Chemgenex takeover bid from 242,463,072 shares (77.32%) to 259,363,150 shares (82.72%).
Cephalon said it had increased Chemgenex listed options acceptances from 9,428,275 options (86.11%) to 9,463,604 options (86.43%).
The bid is conditional on receiving 90 percent of shares and options.
Cephalon can remove conditions at any time.
Chemgenex fell half a cent or 0.7 percent to 69.5 cents.

PHARMAXIS

Pharmaxis has requested a trading halt pending an announcement “in relation to its European marketing application for Bronchitol for the treatment of cystic fibrosis”.
Trading will resume on May 25, 2011 or on an earlier announcement.
Pharmaxis last traded at $2.93.