Biotech Daily

Wednesday April 24, 2013

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: ALCHEMIA UP 9%, PHARMAXIS DOWN 52%**

*** PHARMAXIS FALLS 52% ON FAILED BRONCHIECTASIS TRIAL**

*** PATRYS MOVES TO 3rd MULTIPLE MYELOMA DOSE**

*** EURO PATENT FOR PHYLOGICA'S AP-1 PHYLOMERS**

*** BIONICHE INVESTOR CONCERN**

*** CONSEGNA EXPECTS $510k FEDERAL R&D TAX REFUND**

*** INVION IND FOR INV103 (CPN10) FOR LUPUS**

*** PRIMA APPOINTS PROF KOHRT, DR KLEIN CLINICAL ADVISORS**

MARKET REPORT

The Australian stock market climbed 1.72 percent on Wednesday April 24, 2013 with the S&P ASX 200 up 86.2 points to 5,102.4 points.

Ten of the Biotech Daily Top 40 stocks were up, 15 fell, 11 traded unchanged and four were untraded.

Alchemia was the best, up three cents or 8.6 percent to 38 cents with 604,798 shares traded.

Benitec climbed 7.7 percent; Genetic Technologies was up 6.7 percent; Mesoblast rose 5.6 percent; Atcor, Cellmid and CSL were up more than three percent; Prima and Resmed climbed more than one percent; with QRX, Reva and Sirtex up by less than one percent.

Pharmaxis led the falls, down 16.5 cents or 52.4 percent to 15 cents with 26.6 million shares traded, followed by Impedimed down 20 percent to 5.2 cents, with 3.5 million shares traded and GI Dynamics down 11.6 percent to 61 cents with 65,701 shares traded.

Tissue Therapies lost 7.1 percent; Osprey and Patrys were down more than six percent; Viralytics was down five percent; Optiscan and Phosphagenics fell four percent or more; Nanosonics was down 3.3 percent; Living Cell, Starpharma and Universal Biosensors shed two percent or more; Bionomics was down 1.3 percent; with Acrux and Cochlear down by less than one percent.

PHARMAXIS

Pharmaxis fell 52.4 percent on news that its phase III trial of Bronchitol for bronchiectasis did not meet its primary endpoint of exacerbation reduction.

Pharmaxis said that it achieved a non-significant (p = 0.31) eight percent difference in the rates of defined pulmonary exacerbations in patients treated over a 12 month period, when comparing twice-daily inhaled Bronchitol (400mg mannitol) to control (50mg mannitol).

The company said that the top-line results of the 461-patient (of 485 patients recruited), double-blind, placebo-controlled, randomized trial showed statistically significant improvements in four of seven secondary endpoints including time to first exacerbation, days of antibiotic use, quality of life and sputum weight.

Pharmaxis chief executive officer Gary Phillips told a teleconference that unlike the phase III cystic fibrosis trial, the trial did not see “any evidence of a control effect”.

The cystic fibrosis trial reached a p = 0.059 significance level, which the company said at that time could have been affected by mannitol-naïve patients responding to the 50mg control dose (BD: Jun 22, 2010).

Pharmaxis has said that there is no other dry powder available for use as a control.

Today, Mr Phillips said that there were no issues with the trial design and that there were no results that were surprising.

He said that although the eight percent reduction in exacerbations was probably not sufficient to merit treatment the other measures were compelling and there was no other product available for bronchiectasis patients.

“Does Bronchitol work in bronchiectasis?” Mr Phillips asked. “Yes.”

“Is it approvable in this group? No,” Mr Phillips said.

Mr Phillips said that the data needed detailed analysis and a sub-group of patients with greater disease burden could form the basis of discussions with regulators.

In a media release, Pharmaxis said that there were similar overall rates of adverse events between the treatment groups and that Bronchitol had an acceptable safety profile.

Pharmaxis said that the trial was the largest undertaken in bronchiectasis, the first to look at the rate of exacerbations over 12 months and took place in 84 hospitals in Europe, North America, South America, Canada, Australia and New Zealand.

“It is disappointing not to have achieved the primary endpoint in this trial,” Mr Phillips said. “We will therefore not be proceeding immediately with a regulatory submission for bronchiectasis,” Mr Phillips said. “This trial, however, was a global first and is valuable both to Pharmaxis and the health professionals treating patients with bronchiectasis.”

“The very large data set contains more than 43 thousand electronic pages of patient information [and] a full analysis will take some time but encouragingly, available data suggests that Bronchitol performs better in some patients with high disease burden,” Mr Phillips said.

London’s Royal Brompton Hospital consultant respiratory physician Dr Diana Bilton said that bronchiectasis was “a serious and disabling lung condition for which there are very few treatment options”.

“Historically, reducing exacerbations in respiratory conditions like [chronic obstructive pulmonary disease] and bronchiectasis has proven difficult,” Dr Bilton said.

“The secondary endpoints in this study of improving quality of life and increasing the time to suffering an exacerbation are highly clinically relevant and the data suggests that Bronchitol is worth developing in a well-defined patient population,” Dr Bilton said.

Mr Phillips said that the findings would be presented at a scientific respiratory conference.

Pharmaxis has $73,000,000 in cash at March 31, 2013.

Pharmaxis fell 16.5 cents or 52.4 percent to 15 cents with 26.6 million shares traded.

PATRYS

Patrys says a third group of three patients has been approved in its phase I/IIa trial of PAT-SM6 for multiple myeloma.
Patrys said that the approval was based on safety data from its second group of three patients treated in Germany's University Hospital of Würzburg (BD: Dec 10, 2012; Jan 20, Mar 7, 2013)
The company said that each patient in the second group received four doses of PAT-SM6, at a dose level of 1mg/kg and no significant adverse events were reported
Patrys said recruitment of the third group of three patients had begun and each patient would initially receive four doses of PAT-SM6, at a dose level of 3mg/kg.
The company said that the open-label, multi-dose escalation trial was in relapsed and multi-resistant patients with multiple myeloma who had failed all currently marketed drugs and had a very poor prognosis.
Patrys said that initially, 12 patients would be enrolled in four dosing groups and receive a minimum of two cycles or four doses of treatment.
The company said that if a patient showed a partial response to treatment with PAT-SM6 an additional cycle or two doses of treatment would be offered.
Patrys said that the primary objective of the study was to evaluate the safety and tolerability of escalating doses of PAT-SM6 and the secondary objective was to measure efficacy as determined by a series of laboratory assays.
Patrys fell 0.2 cents or 6.45 percent to 2.9 cents with 8.4 million shares traded,

PHYLOGICA

Phylogica says it has been granted a European patent entitled 'Peptide inhibitors of c-Jun dimerization and uses thereof'.
Phylogica said the patent covered its lead Phylomer peptides targeting the AP-1 pathway, which was "a crucial mediator of inflammation and cell death in multiple diseases".
The company said that the AP-1 pathway played a critical role in neuronal cell death caused by stroke and traumatic brain injury and lung inflammation resulting from acute respiratory distress syndrome and septic shock.
Phylogica said the family of Phylomer peptides had demonstrated efficacy in preclinical models for stroke, traumatic brain injury and acute respiratory distress syndrome.
The company said that the granted claims of the patent covered any use of these Phylomers in the treatment of ischemic disease, including stroke, traumatic brain injury and reperfusion injury of liver, heart and blood vessels following transplantation.
Phylogica said that ischemia, or insufficient blood supply, was a cause of inflammation and cell death and the damage was often exacerbated when blood supply returned to the vessel or organ, but the peptides covered by the patent were active in this pathway and helped reduce the collateral damage to tissue.
Phylogica chief executive officer Dr Paul Watt said the European patent provided "further validation of the biological activity of Phylomers against intracellular targets".
"More than half of the discovery alliances that we are currently negotiating … are focused on accessing the intracellular space," Dr Watt said.
"The Phylomer platform could provide a unique source of next-generation biological drugs that can penetrate cells and thus expand the potential target landscape," Dr Watt said.
Dr Watt said Phylogica was working with Janssen in this field and had engaged Bio-Link to support partnering efforts for the anti-inflammatory Phylomers targeting the intracellular transcription factor AP1.
Phylogica was untraded at 1.8 cents.

BIONICHE LIFE SCIENCES

Bioniche says two former Biovail executives claim to represent a group of concerned shareholders and suggest the company engage in open dialogue with all shareholders.
Bioniche said it had received a letter but did not name the executives, republish the letter or explain the connection between Bioniche and Biovail and rejected the approach.
The letter, signed by former Biovail chief executive officer William (Bill) Wells and former general counsel and senior vice-president of corporate development Greg Gubitz, said they represented shareholders owning more than five percent of Bioniche's outstanding common shares.
Under the Australian Corporations Act, ownership of five percent of outstanding shares is the minimum required to requisitions extraordinary general meetings.
Bioniche is listed on the ASX and the Toronto Stock Exchange with the majority of its shares held on the TSX.
The letter presented strong criticism of Bioniche's board management and share price and said that "members of our group executed the extremely successful turnaround of Biovail Corp and subsequent merger with Valeant Pharmaceuticals International, thereby creating billions of dollars in shareholder value for Biovail's shareholders".
The group said it had "decades of experience in the life sciences industry and in fixing troubled businesses [and] our track record of creating value for shareholders is clear".
The letter said Bioniche had a history of losses, with not one year of positive earnings and the share price had lost more than 96 percent of its value since 1996.
The group said it had contacted Bioniche in 2012 to offer advice and provide tangible solutions to fix the company.
"We believed then and believe now that there is considerable potential for Bioniche to become a very successful Canadian life sciences company," the letter said.
"Despite multiple contacts with the management and board, our best efforts to help Bioniche were stalled and dismissed," the letter said.
The letter said that as significant shareholders of Bioniche "we are aware of our rights and the various steps available to us to ensure no further value is destroyed". The letter is at: http://finance.yahoo.com/news/former-biovail-executives-issue-open-120000075.html.
Bioniche said that it had "long been aware of the issues related to the performance of the stock, and the board of directors has been working for a number of months to unlock the inherent value in the company's assets".
Bioniche said that several strategic partnering and investment-related offers had been made and were under review and the company had been in discussions with external advisors and a major US investment bank was being engaged to manage the process.
The company said that the work done over the past several months "has given the board of directors comfort that there is significant value within the company".
"The individuals behind the letter have had access to confidential corporate information within the past few months and have made two overtures to the company which do not favorably compare to the opportunities under review," Bioniche said.
Bioniche was untraded at 23 cents.

CONSEGNA GROUP

Consegna says it expects to receive $510,000 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Consegna said that the rebate related to research and development expenditure on its Breatheassist technology.
Consegna fell 0.5 cents or 14.3 percent to three cents.

INVION (FORMERLY CBIO)

Invion says it has filed an investigational new drug application to the US Food and Drug Administration for INV103 for systemic lupus erythematosus

Invion said that INV103 was a modified version of the naturally occurring human protein, chaperonin10 (Cpn10), which was developed by the then CBio as XToll for rheumatoid arthritis but failed to meet its endpoints (BD: Aug 1, 2011).

Today Invion said that if the investigational new drug application was accepted, it would enable Invion to begin phase II clinical studies in patients with lupus.

Invion chief executive officer Dr William Garner said the submission was “a major milestone”.

The company said that the submission was chief medical officer Dr Mitchell Glass’s fiftieth investigational new drug application and Dr Glass had received marketing authorization for five new drug applications to the FDA.

“We believe the data to date clearly demonstrates that the investigation of INV103 as a therapy for lupus is warranted and we look forward to continuing our work to elucidate clinically meaningful results for this drug,” Dr Glass said.

Invion said that lupus was a vascular inflammatory disease that led to chronic inflammation, antibody production and tissue damage.

The company said that the disease occurred more commonly in women and increased the risk of other health problems including heart disease, kidney disease and osteoporosis, with a market predicted to reach sales of more that $4 billion by 2020.

Invion was untraded at 5.5 cents.

PRIMA BIOMED

Prima says Prof Holbrook Kohrt and Dr Pamela Klein have been appointed as senior clinical advisors for the CVac development programs.

Prima said that Prof Kohrt and Dr Klein would work with Prima chief technology officer Dr Sharron Gargosky to guide the ongoing ovarian cancer clinical trials, interpret clinical and immunological data coming from the ongoing CAN-003 phase II/III trial and help develop the strategy and clinical design of the planned phase II pilot trials of CVac in additional cancer targets.

Prima said that Dr Klein was the founder and president of PMK Bioresearch and was previously the chief medical officer at Intellikine and Genentech’s development vice-president.

The company said Dr Klein qualified as a medical doctor at Loyola University in Chicago.

Prima said that Prof Kohrt was a professor of medicine in oncology at Stanford University School of Medicine.

The company said that Prof Kohrt qualified as a medical doctor and earned a Doctoriate of Philosophy in clinical trial design and tumor immunology from Stanford University.

Prima said that Prof Kohrt was the primary investigator on a number of National Institutes of Health and industry sponsored oncology trials and has published extensively in the fields of cancer immunology and immunotherapy.

Prima was up 0.1 cents or 1.1 percent to 8.9 cents with 1.1 million shares traded.