Biotech Daily

Monday May 13, 2013

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH UP: COMPUMEDICS UP 11%, AVITA DOWN 9%**

*** AUSBIOTECH, INDUSTRY CONCERN WITH NSW TRIAL INSURANCE**

*** STARPHARMA INVESTIGATES SPL7013 FOR VIRAL CONJUNCTIVITIS**

*** JAPAN PATENT FOR NEURODISCOVERY'S ONCOSIL**

*** AUSBIOTECH SECURES 2014 SYDNEY BRAIN-MAPPERS MEETING**

MARKET REPORT

The Australian stock market edged up 0.08 percent on Monday May 13, 2013, with the S&P ASX 200 up 4.2 points to 5,210.3 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 10 fell, 12 traded unchanged and five were untraded. All three Big Caps were up.

Compumedics was the best, up 0.5 cents or 11.1 percent to five cents with 5,000 shares traded.

Anteo climbed 6.15 percent; Uscom was up five percent; Bionomics, Ellex, Genetic Technologies, Prana, Resmed and Sirtex rose more than two percent; Acrux, Cochlear and Heartware were up more than one percent; with Clinuvel, CSL, Medical Developments and Mesoblast up by less than one percent.

Avita led the falls, down one cent or 9.1 percent to 10 cents, with 477,220 shares traded.

Benitec and Pharmaxis lost more than six percent; Osprey was down 5.3 percent; Starpharma fell 4.8 percent; Prima was down 3.4 percent; Nanosonics, Universal Biosensors and Viralytics shed more than one percent; with QRX down by less that one percent.

AUSBIOTECH, NEW SOUTH WALES GOVERNMENT

The New South Wales committee of Ausbiotech is concerned about the doubling of the minimum requirement for clinical trials indemnity insurance from $10 million to $20 million.

Ausbiotech said that New South Wales Health issued the policy directive effective for January 25, 2011 and the industry organization has been attempting to have the Government reverse its decision.

Datapharm Australia is a Sydney-based contract research organization involved in clinical trials and its project manager Luke Edington has been involved in the attempt to convince the New South Wales Government to reverse its decision.

Mr Edington told Biotech Daily that the doubling of the minimum indemnity level to $20 million could effectively add between 45 percent and 55 percent to the cost of an insurance policy for a trial being conducted in New South Wales, relative to the cost of purchasing compliance insurance for the same trial in any other state.

“It is dependent on numerous factors such as size and risk profile, however just as an example, where you would have paid $20,000 for a trial, you may be paying more than $30,000,” Mr Edington said.

Ausbiotech said that the move put New South Wales “out of line with other states and raises the cost of conducting trials … in contrast to the rest of the country”.

In June 2012, the Victoria Government proposed a similar increase but by August had dropped the move.

Ausbiotech chief executive officer Dr Anna Lavelle said at that time that she was “heartened that Victoria did not proceed with the increased insurance coverage requirement to $20 million – and will therefore remain competitive and attractive as a clinical trial destination”.

“The commercial decision to locate a trial is complex and any unnecessary hurdle disadvantages small indigenous companies and trials where a disease state is less common, thereby discouraging their attraction and disadvantaging local patient access. Victoria needs a vibrant, productive, efficient, internationally-competitive and world-class clinical trials industry to support its local competitive advantage in biotech development,” Dr Lavelle said

Ausbiotech said in August 2012 that there were 635 trials underway in Australia, involving 19,000 patients, with more than 320 of the trials in Victoria, giving local access to patients and contributing to the economy.

Ausbiotech said it was working with the Pharmaceuticals Industry Strategy Group and the Clinical Trials Action Group to support national co-ordination of policy on clinical trials across the Australian, state and territory governments and the harmonisation of regulatory requirements to ensure cost reduction and speed to commencement, which will ultimately increase competitiveness globally and make Australia a more attractive destination for trials.

Ausbiotech said that fewer trials taking place in New South Wales would also mean fewer patients in the state participating and accessing innovative therapies.

Mr Edington said that the New South Wales Government required evidence that the increase in the insurance coverage was having an impact on companies and trial and urged biotechnology and related companies to complete the survey at: http://www.researchreceptor.com/quick-survey-help-reduce-the-nsw-clinical-trial-indemnity-insurance-minimum-requirement.

The survey closes on May 31, 2013.

STARPHARMA

Starpharma says SPL7013 has shown potent antiviral effect against adenovirus, the agent responsible for the majority of viral conjunctivitis cases.

Starpharma said that both in-vitro and in-vivo pre-clinical studies had shown that SPL7013, the active ingredient in Vivagel, had “the potential to be a first-in-class anti-viral agent for viral conjunctivitis”.

The company said that adenovirus was the most common cause of viral conjunctivitis, a condition for which there was no known cure.

Starpharma chief executive officer Dr Jackie Fairley said that the results of studies assessing SPL7013 against adenovirus were “very positive and further broaden the potential commercial applications of this dendrimer” which she said had potent activity against HIV, human papillomavirus and herpes simplex viruses.

“Furthermore, feedback from potential partners and clinicians on this opportunity has been very encouraging,” Dr Fairley said.

“Viral conjunctivitis can be a serious and painful condition and today clinicians are without antiviral therapeutic options,” Dr Fairley said.

Starpharma said that SPL7013 had been found to be effective across a range of relevant adenovirus strains, at levels of efficacy that support the development of a therapeutic product targeting viral conjunctivitis.

Starpharma said it had undertaken “some initial formulation work for this product, as well as other activities to support the next round of interactions with potential commercial partners”.

The company said that the bacterial conjunctivitis market was estimated to be worth more than $1 billion dollars a year, but there was no antiviral therapy available for viral conjunctivitis and there was an estimated global market of $700 million for effective viral conjunctivitis treatments.

Starpharma said that adenovirus conjunctivitis was highly contagious, painful and could lead to serious complications including damage to vision and was responsible for a significant proportion of all infectious conjunctivitis.

“The attractiveness of this product opportunity is significantly enhanced by the advanced stage of development of SPL7013 as Vivagel for other indications,” Dr Fairley said.

“We have already compiled a very extensive [new drug application] data package around the pharmacology, toxicology and manufacture of Vivagel which would minimize incremental costs, expedite the development path for this product and increase its appeal to commercial partners,” Dr Fairley said.

Starpharma has previously told the ASX that Vivagel failed to meet its primary endpoints in a phase III trial for bacterial vaginosis and a phase II trial for recurrence of bacterial vaginosis (BD: Nov 28, 2012; Apr 3, 2103).

The company has a licence agreement with Japan’s Okamoto and Ansell for the potential use of Vivagel as a condom coating, which was under regulatory review, and the company previously sought to commercialize Vivagel for use against AIDS in Africa (BD: May 19, Aug 18, 2011).

Starpharma said it was “continuing to advance Vivagel for bacterial vaginosis applications, following positive phase II results last month”.

The company said that planning was underway for the phase III clinical trials for the prevention of recurrence indication of Vivagel and the opportunity for symptomatic relief continued to be actively explored.

Starpharma fell 4.5 cents or 4.8 percent to 88.5 cents.

NEURODISCOVERY

Neurodiscovery says its wholly-owned UK subsidiary Enigma Therapeutics has been granted a Japanese patent entitled 'Devices and methods for the treatment of cancer'.
Neurodiscovery said that the patent, which had been granted in the US, Europe, Australia, New Zealand, Singapore and Canada, gave further protection to Enigma Therapeutics key anti-cancer technology Oncosil, until February 2022.
The company said that the granted patent claimed "an internal therapeutic product for the treatment of cancer by brachytherapy (intra-tumoral injection) comprising a radionuclide anti-cancer component that is located in a microparticle".
In February, Neurodiscovery said it would acquire Engima, whose lead product, Oncosil was a targeted brachytherapy treatment developed under a licence from Psivida's Psimedica for its Brachysil product (BD: Feb 20, Apr 16, 2013).
Neurodiscovery executive chairman Roger Aston said the company was "pleased to have further strengthened our intellectual property protection for this important technology as we now enter the next key phase of the clinical development of Oncosil".
Neurodiscovery was untraded at 3.3 cents.

AUSBIOTECH

Ausbiotech says Australia will host its first World Congress of the Society for Brain Mapping and Therapeutics meeting in Sydney, in March 2014.
Ausbiotech acting chief executive officer Glenn Cross made the announcement at the Society's meeting in Baltimore, Maryland.
"This is a big win for Australia and Ausbiotech is honored to be asked to organize this important international event," Mr Cross said.
"It will provide an opportunity for Australian life sciences experts to showcase their work and advancements on the world-stage," Mr Cross said.
The industry organization said that the meeting would be a multidisciplinary forum to encourage knowledge sharing among specialists and industry to further advances in brain and spinal cord mapping and image-guided therapies, attracting physicians, scientists, policy makers and funding agencies to 40 sessions with more than 200 speakers.
Ausbiotech said that the theme for the 2014 Congress will be 'Brain Therapeutics – bringing together engineering, science and medicine'.
Ausbiotech said that the program would highlight neuroscience, engineering, neurosurgery, psychiatry, psychology, molecular biology, neurology, radiology and oncology and feature emerging areas such as nano-biotechnology, stem cell and regenerative medicine, molecular psychiatry and micro-surgery.
The industry organization said that the meeting would held at Sydney's Four Seasons Hotel, from March 17 to 19, 2014.
For more information on bookings, abstract submissions, or exhibition and partnerships, contact Ausbiotech events manager Kirsty Grimwade at: kgrimwade@ausbiotech.org.