Biotech Daily

Tuesday August 12, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ANTEO UP 11%, AVITA DOWN 9%**

*** NEUREN PREPARES FOR US IND FOR NNZ-2591**

*** FSHD $300k TAKES NOVOGEN TO NEURO-MUSCULAR INDICATIONS**

*** ORTHOCELL OPENS ON ASX, CHINA ROYALTY, SUBSTANTIALS**

*** BRENDAN MORAN TAKES 6% OF LBT**

*** CORRECTION: NANOSONICS**

MARKET REPORT

The Australian stock market climbed 1.34 percent on Tuesday August 12, 2014 with the S&P ASX 200 up 73.3 points to 5,530.3 points.

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

Anteo was the best, up 1.5 cents or 10.7 percent to 15.5 cents with 4.7 million shares traded.

GI Dynamics climbed 7.1 percent; Analytica rose 6.1 percent; Prima was up five percent; Ellex, Prana and Psivida were up more than four percent; both Admedus and Antisense were up 3.57 percent; Bionomics, Clinuvel, CSL, Mesoblast, Phosphagenics, Resmed and Sirtex rose two percent or more; Benitec, Medical Developments and Pharmaxis were up more than one percent; with Cochlear and Nanosonics up by less than one percent.

Avita led the falls, down one cent or 8.7 percent to 10.5 cents with 225,344 shares traded, followed by Universal Biosensors down 8.3 percent to 16.5 cents with 126,392 shares traded.

Compumedics fell four percent; Genetic Technologies lost 3.6 percent; Neuren, Starpharma and Tissue Therapies were down more than one percent; with Alchemia down by 0.9 percent.

NEUREN PHARMACEUTICALS

Neuren says it has begun activities supporting a filing of an investigational new drug application to the US Food and Drug Administration for NNZ-2591.

Neuren chief financial officer Jon Pilcher told Biotech Daily that the company “has not yet decided on the indication for the IND”.

“It would be a neurological disease and could be NNZ-2591 developed for a range of potential indications,” Mr Pilcher said.

Neuren said that it would focus on optimization of manufacturing processes and physical attributes for NNZ-2591, a di-peptide related to insulin-like growth factor 1 (IGF-1) and NNZ-2566, which was in phase II trials for four neurological indications including traumatic brain injury, Rett syndrome and Fragile X syndrome.

The company said that like NNZ-2566, NNZ-2591 exhibited “potent neuro-protective, neuro-restorative and pro-cognitive effects which resulted from the inhibition of inflammation and cell death as well as normalization of synaptic plasticity and neuronal signalling.

Neuren said that results from studies at the US Walter Reed Army Institute of Research reinforced and expanded the understanding of the mechanisms of action of NNZ-2591.

The company said that NNZ-2591 had shown positive results in well-validated preclinical models of cognitive impairment, Fragile X syndrome, traumatic brain injury, stroke, Parkinson’s disease and peripheral neuropathy and encouraging results had been achieved in two studies in a model of multiple sclerosis.

Neuren said that multiple sclerosis was an autoimmune disease caused by destruction of the myelin sheath that surrounds nerve fibres and facilitated cell-signalling in the brain and spinal cord and resulted in impairment of motor function as well as cognitive impairment.

The company said that multiple sclerosis took two forms, relapsing-remitting and progressive, affecting about 85 percent and 15 percent of cases, respectively.

Neuren said that recently completed experiments tested two dose levels of NNZ-2591 in the experimental autoimmune encephalitis model of multiple sclerosis and included both relapsing-remitting and progressive studies.

The company said that in the relapsing-remitting model, both dose levels of NNZ-2591 resulted in an average reduction of approximately 30 percent in neurological impairment compared to vehicle.

Neuren said that in the spinal cord and brain, the number of inflammatory foci was reduced by an average of approximately 30 percent and 48 percent, respectively.

The company said that in the progressive model, which tended to be more resistant to treatment, the higher dose level of NNZ-2566 resulted in an average reduction of about 30 percent in neurological impairment compared to vehicle.

Neuren said that testing of the effect of treatment on demyelination in the spinal cord and brain was inconclusive in both studies, due to low levels evidenced during the study.

The company said that in addition to preclinical evidence of strong therapeutic potential in a range of applications and an apparently promising safety profile, NNZ-2591 had a number of pharmacological attributes that made it an attractive candidate for further development, including “excellent oral bioavailability [of] approximately 100 percent, likely suitability for development of a solid oral dosage form and potential for improved stability compared to other peptide-like compounds.

Neuren executive chairman Dr Richard Treagus said that whilst the company’s near-term focus “remains the current phase II clinical trials of NNZ-2566 in four different indications, the attractive pharmaceutical properties and pre-clinical efficacy of NNZ-2591 make a compelling proposition to advance its development behind NNZ-2566”.

Neuren fell 0.1 cents or one percent to 9.5 cents with 7.3 million shares traded.

NOVOGEN

Novogen says the Sydney-based FSHD Global Research Foundation will fund it to find treatments for musculo-degenerative diseases including facio-scapulo-humeral dystrophy.

Novogen did not specify the level of the grant but a company spokesman told Biotech Daily that FSHD was “providing special funding over and above their normal $300,000”.

The company said facio-scapulo-humeral dystrophy was one of the most common forms of muscular dystrophy and affected about seven in 100,000 people.

Novogen said the funding would support a collaboration with Genea Biocells, which had developed “the first accurate laboratory model” of facio-scapulo-humeral dystrophy using embryonic stem cells donated by FSHD-affected families, which would enable Novogen to screen its libraries of super-benzopyran drugs for active compounds.

Novogen said its primary focus would continue to be oncology, but it had created a ‘Project Jacob Hope’ division to pursue therapies for neurodegenerative, musculo-degenerative and regenerative medicine opportunities, headed by Dr Stephen Palmer.

The company said the common link between oncology and the Project Jacob Hope indications was “the recent breakthrough discovery that the company’s super-benzopyran drug technology library holds compounds with a dual ability to modify the activity of tissue stem cells and to protect normal tissue from the toxic stresses of the disease process”.

Novogen chief executive officer Dr Graham Kelly said the company “designed the super-benzopyran compounds in order to create the first family of drugs capable of reaching back past regular cancer cells, to their parent cells, the so-called tumor-initiating cancer cells”.

“These are cells that possess all the characteristics of tissue stem cells, but unlike their regular daughter cancer cells, are completely resistant to radiotherapy and chemotherapy,” Dr Kelly said. “These are the cells that lead to recurrent disease after apparently responding to initial therapy ... [and] recurrent disease can rarely be treated.”

“For the first time, we are seeing the full range of cancer cells within a tumor respond to the one form of therapy, an effect that we believe will prevent recurrent cancer,” Dr Kelly said.

“In the course of those studies, we came to realize that the action of these drugs in killing cancer stem cells was more than just a blunt cytotoxic effect,” Dr Kelly said. “It was part of a much more intricate mechanism of action that has to do with the ability of these compounds to control the growth and development of stem cells into their adult cell type.”

“Then going on to protect those adult cells from stress induced by abnormal gene activation, as is found in [facio-scapulo-humeral dystrophy],” Dr Kelly said.

Dr Kelly said the company had the opportunity to promote the activity of a patient’s own tissue stem cells, without the challenges and hurdles of stem cell transplantation.

Dr Stephen Palmer said that in muscular dystrophies, like facio-scapulo-humeral dystrophy, the body eventually succumbed to the underlying disease process because the body’s skeletal muscle stem cells became exhausted trying to repair the constant damage to the muscle fibres caused by the underlying genetic abnormality.

“The approach we are adopting is to develop a means of promoting the growth and development of those stem cells while reducing the impact of the constant damage to the adult fibres,” Dr Palmer said.

This two-pronged attack is an entirely novel and exciting approach,” Dr Palmer said.

Dr Kelly said that Project Jacob Hope was a broad program of which the collaboration with FSHD Global Research was “just one part”.

“We are investigating the same technology to treat a range of other muscular dystrophies as well as neurodegenerative diseases including Alzheimer’s,” Dr Kelly said.

Novogen was up one cent or eight percent to 13.5 cents.

ORTHOCELL

According to Commonwealth Securities, Orthocell opened down one cent or 2.5 percent from its initial public offer price of 40 cents on its first day of trade on the ASX.
Orthocell raised $8 million to develop autologous stem cell treatments for tendon, cartilage and soft tissue injuries (BD: Apr 16, May 29, 2014).
The company said it had received its first royalty revenue from the Guangzhou, China-based Grandhope Biotech under the 2013 licencing agreement for the use of its autologous tenocyte implantation, Ortho-ACI, in China.
Orthocell closed down four cents or 10 percent to 36 cents with 681,953 shares traded.

ORTHOCELL

Director Matthew Callahan and Stone Ridge Ventures have become substantial shareholders in Orthocell with 10,179,559 shares (12.34%).
Mr Callahan's substantial shareholder notice said he was based in Haverford Pennsylvania and that he was the founder and director of the Balcatta, Western Australia-based Stone Ridge which was the manager of the SRV Tech trust and the registered sharholders were SRV Custodians and SRV Nominees.
The Nedlands, Western Australia-based director Paul Anderson and Nicole Telford said they became substantial shareholders in Orthocell with 6,963,608 shares (8.44%).
The City Beach, Western Australia-based director Qi Xiao Zhou said he had become a substantial shareholder in Orthocell with 5,955,673 shares (7.22%).

LBT INNOVATIONS

The Rose Bay, Sydney-based Brendan Moran and Morcap Pty Ltd have become substantial shareholders in LBT with 6,363,571 shares or 5.55 percent.
The substantial shareholder notice said that Mr Moran was a 50 percent owner of Morcap, which held 440,496 of the shares.
Mr Moran said the shares were acquired between April 24 and August 7, 2014 with the largest single purchase on August 7 of 1,037,037 shares for $140,000 or 13.5 cents a share.
LBT was up 1.5 cents or 12 percent to 14 cents.

NANOSONICS

Last night's edition accidentally provided wrong information on Nanosonics' trading yesterday.
Yesterday, Nanosonics climbed half a cent or 0.6 percent to 82 cents, not as stated.
The mistake was made by the former Monday sub-editor and Biotech Daily apologizes unreservedly for any confusion caused.
Today, Nanosonics was up a further half a cent or 0.6 percent to 82.5 cents.