

# **Biotech** Daily

## Tuesday August 14, 2012

Daily news on ASX-listed biotechnology companies

\* ASX UP, BIOTECH DOWN: USCOM UP 25%, CLINUVEL DOWN 7%

# \* BURNET INSTITUTE DEVELOPING PREVENTATIVE HEP C VACCINE

- \* SOSEI ASSIGNS NEURODISCOVERY NSL-043 TO BEIJING TIDE
- \* A-BIO INVESTS \$5m IN NUSEP'S PLASMA PLANT
- \* HALL PHOENIX DILUTED BELOW 5% OF BONE

### MARKET REPORT

The Australian stock market was up 0.21 percent on Tuesday August 14, 2012 with the S&P ASX 200 up 8.9 points to 4,292.2 points.

Ten of the Biotech Daily Top 40 stocks were up, 14 fell, 13 traded unchanged and three were untraded. All three Big Caps were up.

Uscom was the best, up three cents or 25 percent to 15 cents with 25,000 shares traded.

Bioniche climbed 6.3 percent; Cellmid, Reva and Sirtex were up more than five percent; Acrux, Avita and Phylogica were up more than three percent; Bionomics and Cochlear rose more than two percent; with Alchemia, CSL and Resmed up more than one percent.

Clinuvel led the falls, down 11 cents or 6.8 percent to \$1.50 with 16,090 shares traded.

Allied Health, Antisense, Ellex, Heartware and Mesoblast lost five percent or more; Genetic Technologies and Universal Biosensors fell more than four percent; Prana was down 3.1 percent; Circadian and Sunshine Heart shed more than two percent; Starpharma and Tissue Therapies were down more than one percent; with Pharmaxis down 0.9 percent.

### **BURNET INSTITUTE**

Melbourne's Burnet Institute says its researchers have developed a potentially preventative vaccine candidate for a number of different strains of hepatitis C. The Institute said a team led by virologist Prof Heidi Drummer developed the candidate hepatitis C vaccine based on their discovery of a third, highly variable region in the hepatitis C virus envelope protein (E2) and detailed studies of the structure and function of the protein.

The Burnet Institute said the research demonstrated that all three of the variable regions of E2 contributed to the immune evasion characteristic of hepatitis C, but were not required for the virus to bind to its receptor on cells, and therefore were not an essential target of antibodies.

The Institute said that by deleting all three of the variable regions at once, they had been able to make a candidate vaccine that induced high levels of neutralizing antibodies against all strains of hepatitis C, which had not been possible with previous approaches. "Hepatitis C has a great ability to change its structure and evade the immune response," Prof Drummer said. "This makes vaccine development challenging."

"Our vaccine is unique as it contains only the most essential, conserved parts of the major viral surface protein, eliciting antibodies that prevent both closely and distantly related hepatitis C viruses from entering cells, thereby preventing infection," Prof Drummer said. The Burnet Institute said the vaccine candidate was in formal pre-clinical studies and "could be the first ever preventative vaccine for the virus".

The Institute said that hepatitis C affected about 200 million people globally and a preventative vaccine had the potential for a significant impact.

The Burnet Institute said Prof Drummer released the details about the hepatitis C vaccine project at the Immunotherapeutics and Vaccine Summit in Cambridge, Massachussets on August 13, 2012.

#### **NEURODISCOVERY**

Neurodiscovery says Japanese partner Sosei Corp had assigned the intellectual property rights for neuropathic pain drug NSL-043 to China's Beijing Tide Pharmaceutical Co. Neurodiscovery said that Sosei maintained a potentially significant interest in the commercial outcome of any clinical success and it also benefited to the extent of its current agreement with Sosei, but no fee had been paid to Sosei at this stage.

In 2010, Neurodiscovery handed its neuropathic pain drug NSL-043 back to Japan's Sosei Corp and said it was reviewing NSL-101 for dental pain (BD: Mar 18, 2010).

In 2009 the company said it would not commit to a phase II trial of NSL-043 for neuropathic pain and its ownership fell to about 32 percent.

Neurodiscovery said that with Sosei it completed two phase I trials, in addition to pivotal pre-clinical efficacy data for NSL-043 and that "for financial reasons alone" it terminated the collaboration agreement with Sosei and entered into an assignment agreement with respect to all the intellectual property for NSL-043.

Neurodiscovery said that Sosei had agreed that, for the life of the granted patent(s) and in any or all jurisdictions where they were maintained, about 32 percent of any future revenue would be paid to Neurodiscovery.

The company said that Beijing Tide intended to conduct a proof of principle phase II clinical trial and would maintain the current patent portfolio world-wide and that with clinical success or commercialization in China, Sosei might choose to have certain territories outside China returned.

Neurodiscovery was up 0.3 cents or 14.3 percent to 2.4 cents.

#### <u>NUSEP</u>

Nusep says Singapore's A-Bio Pharma Pte Ltd will invest S\$6million (\$A 4.6million) for 10 percent of its Singapore plasma fractionation subsidiary, Prime Biologics Pte Ltd Nusep said A-Bio Pharma was a subsidiary of Luye Pharma Group and the investment valued Prime at S\$60 million.

The company said the investment consisted of a S\$3.5 million fit out and equipment for the A-Bio facility and a further S\$2.5m for the facility's current good manufacturing practice approval documentation.

Nusep said the facility was previously approved to manufacture therapeutic products by the Singapore Health Sciences Authority and it was expected that the previous approval would shorten the time to market for Prime by at least six months.

Nusep said it would issue Luye with 6,000,000 shares in Prime for the S\$6 million investment which was a 10 percent shareholding in Prime.

The company said it held the remaining 90 percent, but expected to sell the holding down to about 50 percent as additional investors subscribed for shares in Prime and Luye had an option to increase its shareholding from 10 percent to 20 percent by investing a further S\$6 million in Prime shares.

Nusep chairman John Manusu said the investment was "a critical milestone as it represents the first investment by a [pharmaceutical] company into our Prime technology and signals the start of operations in Singapore".

Nusep managing-director Dr Hari Nair said the \$46 million Prime valuation was "only for the therapeutic plasma application of Nusep's Prime technology and doesn't include any other applications such as recombinant therapeutics."

The company said the S\$6 million investment by Luye would allow Prime to establish a physical presence for Prime Biologics in Singapore, start the preparation work for the A-Bio manufacturing facility, place orders with Nusep for S\$1.1 million of Prime manufacturing units, place orders with Nusep for separation membranes and appoint key personnel.

Nusep said the A-Bio facility was about 2,000 square metres therapeutic manufacturing facility, purpose-built by the Singapore Government in 2000 to meet the world regulatory standards and was a state-of-the art current good manufacturing practice registrable therapeutic manufacturing facility.

The company said that Prime was in the process of finalizing negotiations to lease the A-Bio space from Ascendas-REIT, the Singaporean landlord, and expects to complete this transaction by mid-September 2012.

Nusep said that the facility previously had been validated by the Singapore Health Sciences Authority to comply with current good manufacturing production, regulatory approval required before therapeutic manufacturing could be undertaken.

The company said that Prime would install the fractionation units and then apply to have the facility revalidated by the Singapore Health Sciences Authority.

Nusep said the facility was large enough that Prime will be able to run two production lines - one for normal regulated plasma and a second for the Indian currently unprocessable plasma product.

The company said that ABS Novacell Biopharmaceuticals had made significant progress in its funding, which would focus on establishing an Indian Prime facility and in the meantime, ABS and Nusep were finalising the Indian currently unprocessable plasma supply agreement.

Nusep said that the acquisition of the A-Bio facility should enable Prime to process the Indian currently unprocessable plasma material at least six months ahead of time. Nusep was up 2.5 cents or 55.6 percent to seven cents with 330,000 shares traded.

BONE MEDICAL

Hall Phoenix Inwood's 16,210,505 shares in Bone has been diluted below five percent through further use of its La Jolla Cove draw down facility.

Hall Phoenix previous substantial shareholder notice said the company increased from 13,198,457 shares (7.95) to 16,210,505 shares (5.42%).

Bone was unchanged at 0.4 cents.