Biotech Daily

Tuesday April 26, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ANTEO UP 21%, NEUREN DOWN 24%**

*** NEUREN: 'TROFINETIDE SAFE, NO EFFICACY FOR TBI', DOWN 43%**

*** AVIRAGEN (BIOTA) TRADES INAVIR ROYALTY FOR $26m**

*** NUSEP TAKES PRIME TRANSACTION TRADING HALT TO SUSPENSION**

MARKET REPORT

The Australian stock market fell 0.3 percent on Tuesday April 26, 2016 with the ASX200 down 15.8 points to 5,220.6 points.

Six of the Biotech Daily Top 40 companies were up, 25 fell, seven traded unchanged and two were untraded.

Anteo was the best, up one cent or 20.8 percent to 5.8 cents with 5.95 million shares traded.

Opthea climbed 7.5 percent; Medical Developments, Nanosonics and Prana rose more than two percent; with Clinuvel and Resmed up more than one percent.

Neuren led the falls (see below), falling 4.5 cents or 42.9 percent to six cents before closing down 2.5 cents or 23.8 percent to eight cents with 23.2 million shares traded, followed by Airxpanders down 12 cents or 11.2 percent to 95 cents with 195,570 shares traded.

Living Cell and Tissue Therapies lost more than seven percent; Osprey fell 6.9 percent; Antisense, Atcor and Mesoblast were down more than five percent; Benitec, Cellmid, Orthocell and Pharmaxis fell four percent or more; Actinogen, Admedus, Impedimed, Oncosil, Sirtex and Universal Biosensors were down more than three percent; Acrux and Compumedics shed more than two percent; Bionomics, Ellex, IDT and Viralytics were down more than one percent; with Cochlear, CSL and Starpharma down by less than one percent.

NEUREN PHARMACEUTICALS

Neuren says its US Army-supported, 260-patient, phase II, 'Intrepid' trial of trofinetide, formerly NNZ-2566, for traumatic brain injury showed safety but not efficacy.

Neuren said that trofinetide met the primary endpoint of safety, with no treatment-related or dose-dependent trends in adverse events but "did not demonstrate a difference between drug and placebo in the three core efficacy measures".

The company said the three core measures were the Extended Glasgow Outcome Scale, the Mayo-Portland Adaptability Inventory, and Mortality, but efficacy was shown in the Repeatable Battery for the Assessment of Neuropsychological Status.

Neuren said that two contributing factors appeared to be the patient composition and drug levels, with "a higher than expected proportion of patients who were severely injured and, in particular, subjects who had sustained severe injuries to the chest and other parts of the body and were less likely to respond positively to a drug targeting brain injury".

The company said that there was a higher proportion of severely-injured patients in the drug group, in the 200-subject cohort on the highest dose, and while the imbalance was included in the analysis, the adjustment "only partially compensated for the disadvantage".

In a 'Shareholder Update' Neuren said that "all expenditure related to the concussion program [at Fort Bragg, North Carolina] has been placed on hold" and that further development in the brain injury indications would be determined following additional analysis of the Intrepid data and discussions with the US Army on the funding and execution of future trials, including the current concussion trial at Fort Bragg.

On December 24, 2008, Neuren said its then lead product and trofinetide predecessor, Glypromate equalled placebo in its 325-patient phase III trial for neuro-protection in cardiac surgery, and in relation to reducing cognitive impairment in cardiopulmonary bypass surgery patients "Glypromate had no observable effect".

The company said in 2008, that in contrast to the incidence of deficits reported in the literature, only a small proportion, about 20 percent, evidenced any degree of cognitive decline at 12 weeks and, among those with decline, the average change was small, which was attributed to improvements in the surgery (BD: Jan 16, 2009).

In its Shareholder Update, Neuren said the Intrepid trial was co-designed with the US Army in 2009 and further understanding of the drug's actions led to the change of strategy from brain injury to Rett and Fragile X syndrome, which was "reinforced by … discussions with pharmaceutical companies".

In 2014, Neuren said its 53-patient, NNZ-2566 phase II trial for Rett syndrome was safe, well-tolerated and the higher dose met several secondary efficacy endpoints and although granted orphan drug designation, in 2015 failed to win US Food and Drug Administration breakthrough therapy status (BD: Nov 12, 2014; Mar 2, 2015).

Earlier this month the company began a 64-patient, phase II trial of trofinetide in children and adolescents with Rett syndrome (BD: Apr 7, 2016).

Last year, Neuren said its 70-patient trial of trofinetide showed safety and "beneficial effects" for Fragile X syndrome and said it would trial higher doses (BD: Dec 7, 2015).

Today, Neuren said the Intrepid trial showed significantly higher trofinetide clearance from brain injury patients than healthy volunteers, Rett and Fragile X syndrome patients, possibly caused by the volume of fluid replacement and diuretics used in acute critical care, resulting in lower exposure to the drug than targeted.

The company said that further analysis would help define the optimum population, dose levels, treatment duration and efficacy measures should another trial be conducted and it was in discussions with the US Army on the feasibility of funding and executing a trial.

Neuren fell as much as 4.5 cents or 42.9 percent to six cents before closing down 2.5 cents or 23.8 percent to eight cents with 23.2 million shares traded.

AVIRAGEN THERAPEUTICS (FORMERLY BIOTA PHARMACEUTICALS)

Aviragen says that Healthcare Royalty Partners will pay $US20 million ($A25.95 million) in cash, for an undisclosed portion of royalty rights related to Inavir.

In 2012, Biota merged with Nabi Pharmaceuticals and relocated to the US, ostensibly for its $US54 million in cash, but settling for $US27 million (BD: Sep 18, Oct 30, 2012).

Inavir was launched in Japan by then Biota's partner Daiichi Sankyo in 2010, earning $1.16 million royalties from sales of YEN2.8 billion ($A34,119,600) for the period from the October 19, 2010 launch to 31 December 2010 (BD: Oct 19, 2010; Feb 1, 2011).

Biota said at that time that Inavir was Daiichi Sankyo's registered brand for laninamivir octanoate, previously known as CS-8958

Today, Aviragen said it would use "the non-dilutive proceeds to advance its pipeline of direct-acting antivirals" for infections with limited therapeutic options.

Aviragen chief financial officer Mark Colonnese said the deal "allows us to partially monetize our royalty stream from Inavir for significant cash consideration, while also retaining the opportunity to benefit from future upside potential of the product".

Healthcare Royalty Partners founder and managing partner Todd Davis said that his company had been "following Inavir for an extended period and have seen consistently robust sales growth year-over-year as it has established a leading market position among [influenza] medications in Japan".

In 2012, Biota said that Inavir sales for the year to June 30, 2012 were YEN10.831 billion, compared to YEN7.1 billion for the previous year, delivering a royalty of $4.3 million, up 47.3 percent, compared to the previous year's $2.92 million (BD: Jul 31, 2012).

Last night on the Nasdaq, Aviragen was up nine US cents or six percent to $US1.59 ($A2.06 equivalent to 25.8 cents, before the move to the Nasdaq when the company was trading around $A1.00 a share) with 65,088 shares traded.

NUSEP

Nusep has requested a suspension following its trading halt pending "commercial negotiations in relation to a transaction involving a company asset" (BD: Apr 21, 2016).

Today, Nusep said that the negotiations were "in relation to the potential sale of its B class shares in Prime Biologics Pte Ltd".

Nusep last traded at 1.2 cents.