Biotech Daily

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Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: NEUREN UP 9%, LIVING CELL DOWN 8%**

*** NEUREN CLAIMS STATISTICAL EFFICACY FOR TROFINETIDE FOR RETT**

*** OSPREY EXPECTS TO BREAK EVEN IN 2019**

*** USCOM BEGINS CHINA BP+, SPIROSONIC REGULATORY PROCESS**

*** PARADIGM RECEIVES $1.3m FEDERAL R&D TAX INCENTIVE**

*** CRESO APPOINTS SIN SOLUTION LATIN AMERICA DISTRIBUTOR**

MARKET REPORT

The Australian stock market lost 1.56 percent on Wednesday March 22, 2017, with the ASX200 down 90.1 points to 5,684.5 points.

Ten of the Biotech Daily Top 40 stocks were up, 21 fell, six traded unchanged and three were untraded. All three Big Caps fell.

Neuren was the best, up 0.7 cents or 8.75 percent to 8.7 cents with 23.7 million shares traded.

Prima climbed 3.1 percent; Genetic Signatures and Uscom rose more than two percent; Osprey, Starpharma, Universal Biosensors and Viralytics were up more than one percent; with Airxpanders and Sirtex up by less than one percent.

Living Cell led the falls, down one cent or 8.3 percent to 11 cents with 435,894 shares traded.

Compumedics lost 7.4 percent; Benitec shed 6.25 percent; ITL was down 5.6 percent; Bionomics, Factor Therapeutics and Mesoblast fell four percent or more; Actinogen, Pharmaxis and Psivida were down more than three percent; CSL, Cyclopharm, Opthea, Orthocell, Pro Medicus and Resmed shed two percent or more; Acrux, Atcor, Clinuvel, Cochlear and Oncosil were down more than one percent; with Ellex, Medical Developments and Nanosonics down by less than one percent.

NEUREN PHARMACEUTICALS

Neuren says its 82-patient phase II trial of trofinetide for Rett syndrome has shown statistically significant and clinically meaningful efficacy at the highest dose.

Neuren said the 200mg/kg dose of trofinetide "achieved statistically significant clinical benefit compared with placebo for each of three syndrome-specific efficacy measures, the Rett syndrome behavior questionnaire ($p = 0.042$), the clinical global impression of improvement ($p = 0.029$) and the Rett syndrome domain specific concerns ($p = 0.025$).

Neuren executive chairman Dr Richard Treagus told Biotech Daily there was a dose-related response from 50mg/kg to 100mg/kg and 200mg/kg with the 27 patients in the highest group showing a statistically significant response compared to the 24 patients in the placebo group.

Dr Treagus said that all patients had a 14 day run-in and 42 days of treatment with final measurements taken at day-54 and the results were impressive given the relatively small numbers in the cohorts and the achievement of "p-value" significance.

Charts provided in the Neuren media release show that following the end of treatment symptoms returned and improvement decreased.

Dr Treagus said the next step would be to discuss the results with the US Food and Drug Administration Division of Neurology Products, aiming for a pivotal trial in 2018.

Dr Treagus said the only previous significant drug efficacy results for Rett syndrome was Neuren's earlier trial in adults and adolescents and although there had been other recent trials there was "no drug approved for Rett syndrome" (BD: Nov 12, 2014).

"The important thing for the families and for the Rett syndrome organizations is that this is a massive milestone," Dr Treagus said.

In a media release, Neuren said the trial in girls aged five to 15 years was a double-blind, randomized, controlled study of three doses of trofinetide compared with placebo, and Rett syndrome was "a serious and life threatening condition caused by a gene mutation".

Neuren said the improvements of 15 to 16 percent were clinically meaningful in the short duration trial, with improvement increasing until treatment ceased, suggesting further benefit might be achieved with longer treatment duration.

The company said the results provided "strong evidence of biological activity of the high dose across multiple symptom areas, indicating the potential for disease modification rather than simply addressing isolated symptoms" and that trofinetide was well-tolerated, had a good safety profile, with no dose-limiting effects observed.

The company said that on the motor behavior assessment (MBA) and caregiver top three concerns, improvement in the 200mg/kg group was larger than placebo, but the differences were not statistically significant or clinically meaningful.

Neuren said that the MBA measure did not appear to be sensitive to change in the younger population and it would use the Rett syndrome behavior questionnaire as the primary efficacy measure in a future pivotal trial, with evidence that the MBA might be more appropriate as a measure for older age groups.

Greenwood Genetic Center for Translational Research director Dr Walter Kaufmann, an investigator for this trial, said "there was a clear clinical improvement covering several common symptoms in Rett syndrome, which are known to impair the quality of life of girls affected by the disorder".

"The variety of improved symptoms suggests that trofinetide is a drug that targets mechanisms underlying the disorder rather than a symptomatic medication," Dr Kaufmann said. "The impact of the study goes beyond the suggested efficacy of trofinetide, since it shows the potential of neuro-biologically-based drugs for the treatment of Rett syndrome and other neurodevelopmental disorders," Dr Kaufmann said.

Neuren was up 0.7 cents or 8.75 percent to 8.7 cents with 23.7 million shares traded.

OSPREY MEDICAL

Osprey chief executive officer Mike McCormick says that with a focus on increasing sales he expects the company will break-even by December 31, 2019.

In Melbourne as part of an investor road-show, Mr McCormick told Biotech Daily that the company was focused on US sales of its Dyevert Plus cardiac contrast reduction system, with sales in Europe, Latin America and Australia to follow during the course of 2018.

Mr McCormick said that the Dyvert Plus was approved by the US Food and Drug Administration, the European Medicines Agency and the Australian Therapeutic Goods Administration and the system was able to reduce the amount of dye injected into cardiac patients by up to 40 percent.

He said the company started its sales program in San Antonio in Texas and in two years, the company had the Dyevert Plus system installed in 17 of the city's 23 hospitals.

Mr McCormick said that Osprey had 19 sales representatives working across the US, of which 15 had been appointed since September, following the August $29 million capital raising at 28 cents per Chess depository instrument (BD: Aug 4, Sep 7, 2016).

Mr McCormick said that a number of factors affected US reimbursement, including kidney damage and reduction in repeat hospital admissions with 30 days.

He said that reducing the amount of dye in cardiac procedures reduced the impact on kidney damage, especially in people with pre-existing kidney failure, often related to diabetes.

Mr McCormick said indigenous peoples and obese people were prone to kidney damage and the company started its roll-out by targeting areas where kidney damage was known to exist, including the Southern US states and California.

He said the company hoped to break even by the year to December 31, 2019, which would imply sales of $US25 million with a sales staff of 50 people.

Earlier this month, Osprey said it had revenue of $US585,140 for the year to December 31, 2016 with a net loss after tax of $US11.7 million.

Mr McCormick said the company was continuing to spend funds on research and development but the focus was on sales and he expected revenue for the year to December 31, 2017 to exceed $US1 million.

Osprey's most recent Appendix 4C Quarterly Report said that of $US510,000 of revenue for the year to December 31, 2016, $US206,000 was written in the three months to December 31,2016.

Osprey was up half a cent or 1.2 percent to 42.5 cents.

USCOM

Uscom says it has begun the process of filing submissions to the China Food and Drug Administration for approval to sell its BP+ and Spirosonic devices.

Uscom said that CFDA approval was valid for five years and the approval process was being managed by a specialist Beijing-based regulatory consultant and overseen by the company and China importation and wholesale partner China International Intellectech Corp (CIIC) (BD: Jun 16, 2016).

The company said the China regulatory process was complex and uncertain.

Uscom said that both the BP+ and Spirosonic product suites had Conformité Européenne mark approval and CFDA approved precedent devices, which might accelerate approval.

Uscom said that executive chairman Rob Phillips, distribution manager Denise Pater and customer relations manager Bev Jacobson returned from initial training of eight new distributors, with an order for seven Uscom 1A devices.

Uscom was up half a cent or 2.7 percent to 19 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has received $1,340,314 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Paradigm said the rebate related to research and development activities for the year to June 30, 2016.
Paradigm was unchanged at 45 cents.

CRESO PHARMA

Creso says it has a binding letter of intent with the Sao Paolo, Brazil-based Sin Solution for the marketing, sale and distribution of its cannabinoid food additives.
Creso said that Latin America was “a key market” and the agreement provided a strategic foothold to expand the launch of its cannabinoid-derived food additives into other countries in the region.
The company said it would target Brazil’s privately-insured, middle-class population of 60 million people, giving it a potential market of more than $US800 million.
Creso said that Sin Solution specialized in the market-access, sale and distribution services of health care products in Brazil and across Latin America, and had access to more than 350,000 health professionals and more than 200,000 direct patient contacts in the region.
Creso was up 12.5 cents or 17.9 percent to 82.5 cents with 7.7 million shares traded.