Biotech Daily

Thursday May 25, 2017

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: ADMEDUS UP 6%, PRANA DOWN 8%**

*** MONASH RESEARCH LEADS TO ACS WARNING ON ASSAY HIT PAINS**

*** MELBOURNE UNI: 'CANNABIDIOL WORKS FOR PAEDIATRIC EPILEPSY'**

*** HYDROPONICS, PHOENIX ALLIANCE TO IMPORT CANNABIS PRODUCTS**

*** BIOTRON 1-FOR-4 RIGHTS OFFER TO RAISE $1.6m**

*** SIMAVITA RIGHTS RAISE $848k OF HOPED-FOR $1.4m; TOTAL $2.35m**

*** NEUROTECH SHIPS 1st MENTE AUTISM TO GREECE**

*** SUDA UK MEETING ON ZOLPIMIST FOR INSOMNIA**

*** INVESTORS MUTUAL TAKES 6% OF MAYNE PHARMA**

MARKET REPORT

The Australian stock market was up 0.36 percent on Thursday May 25, 2017 with the ASX200 up 20.6 points to 5,789.6 points.

Ten of the Biotech Daily Top 40 stocks were up, 19 fell, seven traded unchanged and four were untraded.

Admedus was the best, up 1.5 cents or 5.6 percent to 28.5 cents, with 185,315 shares traded.

Oncosil and Orthocell climbed more than four percent; Airxpanders was up three percent; Cyclopharm and Polynovo improved more than two percent; Compumedics and Universal Biosensors were up more than one percent; with Cochlear, Ellex, Resmed and Sirtex up by less than one percent.

Prana led the falls, down 0.4 cents or 7.55 percent to 4.9 cents with 59,000 shares traded.

Avita and Mesoblast lost more than six percent; Living Cell fell 4.2 percent; Benitec and Factor Therapeutics were down more than three percent; Atcor, Impedimed, Medical Developments, Nanosonics and Opthea shed more than two percent; Acrux, Actinogen, Bionomics, Psivida and Starpharma were down more than one percent; with Clinuvel, CSL, Pro Medicus and Viralytics down by less than one percent.

MONASH UNIVERSITY

Monash University says its research has led to the American Chemical Society warning of the dangers of artefacts making assay hits appear useful when they are useless.

Monash University said that 160,000-member "the world's largest scientific society [had changed its editorial policy] in a move that could save government and industry millions of dollars a year in preventing dead-end research".

The University said that research by its Prof Jonathan Baell and the University of Minnesota's Prof Michael Walters identified compounds that could create false positives, leading researchers to waste years optimizing promising-looking drug candidates that could not be developed into drugs for the targeted disease.

The original research was published in the Journal of Medicinal Chemistry in 2010 and Nature in 2014.

The American Chemical Society editorial said that "Studies that omit critical controls against experimental artefacts caused by pan-assay interference compounds may waste years of research effort as useless compounds are progressed".

"The American Chemical Society is eager to alert the scientific community to this problem and to recommend protocols that will eliminate the publication of research articles based on compounds with artificial activity," the Society said.

The editors' letter was co-written by nine editors and entitled 'The Ecstasy and Agony of Assay Interference Compounds' was published in the American Chemical Society journal 'Central Science', with the first page of the article available at: http://pubs.acs.org/doi/abs/10.1021/acscentsci.7b00069.

The 2014 Nature article, headlined 'Chemical con artists foil drug discovery' said that "naivety about promiscuous, assay-duping molecules is polluting the literature and wasting resources" and is available at: http://go.nature.com/2rWFcvx.

"Academic researchers, drawn into drug discovery without appropriate guidance, are doing muddled science," the Nature article said.

"When biologists identify a protein that contributes to disease, they hunt for chemical compounds that bind to the protein and affect its activity," the article said.

The article said that assays screen thousands of chemicals, with hits becoming tools for studying the disease and starting points for treatments.

"But many hits are artefacts, their activity does not depend on a specific, drug-like interaction between molecule and protein [while] a true drug inhibits or activates a protein by fitting into a binding site on the protein," the Nature article said.

"Artefacts have subversive reactivity that masquerades as drug-like binding and yields false signals across a variety of assays," the article said.

The article said that pan-assay interference compounds (Pains) had defined structures, covering several classes of compound, but biologists and inexperienced chemists rarely recognized them, instead the compounds were reported as having promising activity against a wide variety of proteins.

"Time and research money are consequently wasted in attempts to optimize the activity of these compounds," the article said.

"Chemists make multiple analogues of apparent hits hoping to improve the fit between protein and compound, meanwhile, true hits with real potential are neglected [and] the apparent activity of Pains is so seductive that work continues despite published reports explaining that a compound interferes with assays." the article said.

The article concluded that drug discoverers must be more vigilant.

"Molecules that show the strongest activity in screening might not be the best starting points for drugs. Pains hits should almost always be ignored. Even trained medicinal chemists have to be careful until they become experienced in screening," the article said.

UNIVERSITY OF MELBOURNE

The University of Melbourne says that marijuana-derived cannabidiol is effective for paediatric epilepsy, but is no better than existing medications.

The University said that a research team including its chair of paediatric neurology Prof Ingrid Scheffer undertook what is believed to be the first large, randomized, controlled trial of cannabidiol for paediatric epilepsy and found it was statistically significant in reducing seizures compare to placebo.

The research paper, entitled 'Trial of Cannabidiol for Drug-Resistant Seizures in the Dravet Syndrome' was published in the New England Journal of Medicine, with an abstract available at: http://www.nejm.org/doi/10.1056/NEJMoa1611618.

The article concluded that "among patients with the Dravet syndrome, cannabidiol resulted in a greater reduction in convulsive-seizure frequency than placebo and was associated with higher rates of adverse events".

Prof Scheffer told Biotech Daily that comparing the results with the published literature on the existing anti-seizure drugs showed that it was comparable, but not better than, the existing drugs.

Prof Scheffer said that the existing drugs typically had a 40 percent response rate, meaning that patients had a 50 percent or more reduction in convulsive seizures.

She said that the cannabidiol group had a response rate of 43 percent, with the placebo group having a 27 percent response rate.

Prof Scheffer said that if she had a child with convulsive seizures and the top four existing drugs failed, based on the trial data, she would have cannabidiol at the top of the list after the first-line treatment.

The New England Journal of Medicine research article said that Dravet syndrome was a complex childhood epilepsy disorder associated with drug-resistant seizures and a high mortality rate.

The article said the trial randomized 120 children and young adults to either 20mg/kg oral cannabidiol per day or placebo, as well as standard anti-epileptic treatment.

The article said that the primary endpoint was the change in convulsive seizure frequency over a 14-week treatment period, as compared with a four week baseline period.

The study found that the monthly median frequency of convulsive seizures decreased from 12.4 to 5.9 with cannabidiol, as compared with a decrease from 14.9 to 14.1 with placebo ($p = 0.01$).

The research article said that the percentage of patients who had at least a 50 percent reduction in convulsive seizure frequency was 43 percent with cannabidiol and 27 percent with placebo ($p = 0.08$).

The article said that patient overall condition improved by at least one category on the seven-category Caregiver Global Impression of Change scale in 62 percent of the cannabidiol group compared with 34 percent of the placebo group ($p = 0.02$).

The study found that the frequency of total seizures was significantly reduced in the cannabidiol group ($p = 0.03$), but there was no significant reduction in non-convulsive seizures.

The research article said that five percent (three patients) of the patients in the cannabidiol group became seizure-free, with none doing so on placebo ($p = 0.08$).

The study said that adverse events were more frequent in the cannabidiol than in the placebo group, included diarrhoea, vomiting, fatigue, pyrexia, somnolence and abnormal results on liver-function tests.

The abstract said that there were more withdrawals from the trial in the cannabidiol group than the placebo group.

Prof Scheffer said she expected to be involved in a larger trial.

THE HYDROPONICS COMPANY

Hydroponics says that Phoenix Life Sciences will partner with its subsidiary Canndeo “to accelerate the introduction of … medicinal cannabis … into Australia”.
Hydroponics said that the Denver, Colorado-based Phoenix would provide “certified products, formulations, intellectual property and doctor-driven delivery methodologies” and it would benefit from Phoenix’s production facilities and planned roll-out of its cannabis products in North America, as well as explore opportunities to collaborate with medical associations to advance professional development in Australia.
The company said the strategic alliance would allow Phoenix to develop products, formulation, packaging knowledge base, product delivery methodologies, marketing support and brand management in collaboration with Canndeo, while enabling Canndeo to establish a route to deliver medicinal cannabis products in Australia.
Hydroponics said that Phoenix was building production facilities to export cannabidiol products from North America and through the alliance the products would be available in Australia.
The company said that it expected import approvals by the end of the year.
Images included in the Hydroponics media release included vials of fast acting sublingual tablets, oral soft gels, thin film dissolving strips, sublingual spray and transdermal patches.
Hydroponics said that Phoenix wanted “to disrupt mainstream healthcare with vertically integrated pharmaceutical research, development, and production of cannabis-based therapeutics to replace opiate based painkillers, [tetrahydrofuran-inhibitors], anti-inflammatories, biologic medications, antidepressants, and sleep medications”.
The company said that the alliance would “explore opportunities to collaborate with medical associations to assist with the roll-out of products in Australia.
Hydroponics chairman Alan Beasley said he expected partnership “to rapidly accelerate the development of [the] supply chain for importing medicinal cannabis products in Australia through Canndeo, and significantly expands our capabilities to advance intellectual property and research and development into cannabis delivery systems”.
Hydroponics fell 4.5 cents or 13.6 percent to 28.5 cents with 2.1 million shares traded.

BIOTRON

Biotron says it hopes to raise $1.56 million in a partly-underwritten renounceable one-for-four rights issue at two cents a share.
Biotron said that two cents was a 39 percent discount to the one month volume-weighted average price and each new share would come with an attaching option exercisable at six cents by November 30, 2018.
The company said that the rights offer was underwritten to $1 million by CPS Capital Group Pty Ltd which was also the lead manager.
Biotron said that the funds would be used to complete complementary non-clinical assays on samples from its phase II HIV-1 clinical trial, evaluation of compounds against viral diseases including respiratory viruses, Dengue virus and hepatitis B, commercialization and negotiation activities, legal fees, travel, personnel costs and general working capital.
The company said shareholders would have the opportunity to apply for additional shares and attaching options and directors intended to participate in some or all of their entitlement under the rights issue.
Biotron said the record date was May 30, the offer would open on June 2 and close on June 20, 2017.
Biotron fell 0.8 cents or 25 percent to 2.4 cents with 1.4 million shares traded.

SIMAVITA

Simavita says its partly underwritten one-for-seven rights issue at four cents a share has raised $848,109 of the hoped-for $1,435,426 (BD: May 3, 2017).
Earlier this month Simavita said it raised $1,500,000 in a placement at the same price (BD: May 8, 2017).
Today, the company said the eligible holders took up 2,395,224 new Chess depository instruments (CDIs) worth $95,809 along with 2,314,510 CDIs worth $92,580 under the shortfall offer, subject to any cheque dishonours.
Simavita said that Lodge Corporate would acquire 16,493,000 CDIs for $659,720.
The company said that the total shortfall was 14,682,921 CDIs worth $587,317 and it reserved the right to issue shortfall shares within three months.
Simavita fell 0.7 cents or 15.6 percent to 3.8 cents.

NEUROTECH INTERNATIONAL

The Malta-based Neurotech says it has shipped its first Mente Autism device for monitoring and training children with autism to Greece.
Neurotech said that the initial shipment was completed and payment received this week, following the appointment of Greek medical devices specialist Bonvie Group as distribution partner for Greece and Cyprus.
The company said that training of the local distributor's sales teams and medical personnel was underway along with marketing initiatives.
Neurotech chief executive officer Wolfgang Storf said it was "another important milestone for the company as we continue to increase our international reach and enter new markets".
"We will be exploring new commercial avenues with our distribution partner Bonvie to maintain momentum with increased orders in the coming months," Mr Storf said.
Neurotech climbed 5.5 cents or 23.9 percent to 28.5 cents.

SUDA

Suda says it will meet the UK Medicines and Healthcare Products Regulatory Agency on June 21, 2017 to discuss registration plans for Zolpimist for insomnia.
Suda said that Zolpimist was an oral spray of zolpidem tartrate and the company said it would seek advice on the suitability of its regulatory strategy to file for approval of Zolpimist in Europe based on the data that resulted in the product's US Food and Drug Administration approval, together with a small pharmacokinetic study in healthy adults to compare Zolpimist with Sanofi's Silnoct zolpidem tartrate tablet.
The company said that the proposed regulatory dossier was intended to support a marketing authorisation application to either the Agency or the European Medicines Agency.
Suda said it would seek advice from the Agency on the acceptability of the excipients used in the Zolpimist formulation which were listed in the US pharmacopeia.
Suda chief executive officer Stephen Carter said that about 100 million people in the European Union had "some sort of insomnia".
"There remains a significant unmet need for new treatment options, particularly for patients that want rapid onset of sleep, have problems swallowing tablets or have gastrointestinal complications," Mr Carter said.
Suda was unchanged at two cents with 1.1 million shares traded.

MAYNE PHARMA

The Sydney-based Investors Mutual says it has increased its substantial holding in Mayne Pharma from 78,764,139 shares (5.23%) to 94,494,139 shares (6.25%).

Investors Mutual previously said that it held the shares along with Aurora Investment Management which owned 20 percent of Investors Mutual and Pacific Current Group which owned 100 percent of Aurora Investment Management (BD: May 4, 2017).

The company said that registered holders included Sandhurst Trustees, Citicorp Nominees, JP Morgan State Super, State Street and RBC Global Services Australia.

Investors Mutual said it acquired shares between May 2 and 23, 2017 with the single largest purchase on May 3, of 2,710,000 shares for $3,340,888 or $1.23 a share.

Mayne was up half a cent or 0.5 percent to $1.10 with 3.3 million shares traded.