



Biotech Daily

Wednesday July 4, 2018

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: IMUGENE UP 10%; NEUREN DOWN 5%**
- * **PRANA DOSES 1st HUMAN SUBJECT WITH PBT434 FOR PARKINSON'S**
- * **GI DYNAMICS: 'ENDO BARRIER HBA1C, WEIGHT LOSS POST-EXPLANT'**
- * **MEDLAB RECRUITING MARIJUANA NANABIS CANCER PAIN TRIAL**
- * **HAEMALOGIX, TAKEDA RESEARCH MULTIPLE MYELOMA.**
- * **FATIMA DICKEY, RICHARD BAYLES, LAGODA DOWN TO 7% IN CLINUVEL**
- * **COLIN MACKINNON, DONALD KENNEDY EACH TAKE 6.4% IN ALCIDION**
- * **ALCIDION CHAIRMAN RAY BLIGHT INCREASES, DILUTED TO 12%**
- * **GENERA TAKES 'CONVERTIBLE NOTES RAISING' HALT TO SUSPENSION**
- * **NUHEARA LOSES FOUNDER DR MICHAEL OTTAVIANO**
- * **NEUREN: DIANNE ANGUS, PATRICK DAVIES, JENNY HARRY DIRECTORS**
- * **NEUROTECH APPOINTS DR DAVID CANTOR DIRECTOR**

MARKET REPORT

The Australian stock market fell 0.43 percent on Wednesday July 4, 2018 with the ASX200 down 26.8 points to 6,183.4 points. Twelve of the Biotech Daily Top 40 stocks were up, 21 fell, five traded unchanged and two were untraded. All three Big Caps fell.

Imugene was the best, up 0.3 cents or 10.3 percent to 3.2 cents with 19.4 million shares traded. ITL climbed 8.1 percent; Airxpanders and Avita improved more than four percent; Benitec, Impedimed and Pro Medicus were up more than three percent; Clinuvel, Pharmaxis and Polynovo were up more than one percent; with Sirtex and Volpara up by less than one percent.

Neuren led the falls, down 14 cents or 4.95 percent to \$2.69 with 182,711 shares traded. Nanosonics, Opthea and Optiscan fell more than four percent; Compumedics, Cyclopharm, Immutep, Osprey and Universal Biosensors lost three percent or more; Actinogen, Admedus, Dimerix, Factor Therapeutics, Oncosil and Telix shed two percent or more; Bionomics, Cochlear, Ellex, Mesoblast and Orthocell lost more than one percent; with CSL, Cynata, Medical Developments and Resmed down less than one percent.

PRANA BIOTECHNOLOGY

Prana says it has dosed the first cohort of eight volunteers in its phase I trial have of PBT434 for the treatment of Parkinsonian diseases.

Last week, Prana chief medical officer Dr David Stamler told Biotech Daily that the first part of the trial would be a single ascending dose study of up to 48 healthy volunteers, in cohorts of eight subjects per dose, to investigate the pharmaco-kinetics, safety and blood levels of the drug, as well as finding the maximum tolerated dose (BD: Jun 27, 2018).

Dr Stamler said that the second part of the trial would use a multiple ascending dose model with daily dosing of three different levels of PBT434 for one week.

Today the company said that PBT434 was “the first of a new generation of small molecules designed to inhibit the aggregation of alpha-synuclein and tau, critical intracellular proteins that were implicated in neurodegenerative diseases such Parkinson’s disease and atypical parkinsonism.

Dr Stamler said the “first human administration of PBT434 is a major milestone for Prana”.

Prana was unchanged at 4.6 cents.

GI DYNAMICS

GI Dynamics says that of 21 of 31 patients in a Birmingham UK study had continued HbA1c and weight benefit following the removal of the Endobarrier duodenal insert.

GI Dynamics said that the Sandwell and West Birmingham Hospitals’ Dr Robert Ryder presented the data from the ‘UK’s 1st National Health Service Endobarrier Service:

Outcomes in 1st 38 Patients to Reach 6 Months After Device Explant’ study at the American Diabetes Association meeting in Orlando, Florida from June 22 to 26, 2018.

The company said the study was based on the outcome from 38 of the 62 patients who completed six months post Endobarrier removal since the study began in October 2014, of which 31 patients attended the six-month follow-up appointment.

GI Dynamics said the primary outcomes of the blood glucose measure HbA1c, weight and BMI showed a significant reduction at explant and six months post explant compared to baseline values and patients had a significant reduction in systolic blood pressure, with the 20 patients on insulin having “a significant reduction in their daily dosage which remained significant after explant”.

The company said that the 10 patients who did not retain benefit, maintained “some mean reduction in HbA1c”.

GI Dynamics said that “many of the patients who saw their benefit deteriorate reported other personal matters in their lives and 70 percent were diagnosed with depression”.

The company said the study was an extension of the 12-patient poster ‘Maintenance of Efficacy After Endobarrier in UK 1st National Health Service Endobarrier Service’, presented last year (BD: Jun 13, 2017).

“We are pleased to present additional data suggesting that Endobarrier can provide substantial clinical benefit post removal,” Dr Ryder said.

“The mean reduction in HbA1c of 2.5 percent and mean reduction in weight of 16kg are clinically significant, especially as many of these patients’ gains were accompanied by significant reduction in diabetic medications, in particular insulin,” Dr Ryder said.

GI Dynamics chief executive officer Scott Schorer said the data “further reinforces treatment durability of Endobarrier after removal, with 68 percent of patients retaining significant clinical benefit six months after removal”.

“We are pleased that expanded clinical data indicates Endobarrier has a treatment effect that extends beyond the treatment period in many patients,” Mr Schorer said.

GI Dynamics was untraded at 3.4 cents.

MEDLAB CLINICAL

Medlab says recruitment is underway at Sydney's Royal North Shore Hospital for its 30-patient phase I/IIa trial of the marijuana-based Nanabis for cancer pain.

Medlab managing-director Dr Sean Hall told Biotech Daily that the phase 1 trial would recruit five patients and the phase IIa trial would have 25 patients.

In May, Medlab said the trial would test the safety, efficacy and dose tolerance of cancer patients with both managed and unmanaged pain (BD: May 15, 2018).

Medlab said the trial "coincides with separate positive feedback received from doctors who have been prescribing the medicine".

The company said that "feedback from some doctors is that it is proving effective in decreasing reliance on opioids and in its speed of action, aided by delivery through Medlab's nano-particle spray, Nanocelle".

The company said "these developments coincide with yesterday's publication in The Lancet of research into the effectiveness of cannabis use in people with chronic non-cancer pain and who have been prescribed opioids".

The Lancet article, titled 'Effect of cannabis use in people with chronic non-cancer pain prescribed opioids: findings from a 4-year prospective cohort study' specifically did not study cancer pain and "found no evidence of a temporal relationship between cannabis use and pain severity or pain interference, and no evidence that cannabis use reduced prescribed opioid use or increased rates of opioid discontinuation".

The article is available at: <https://bit.ly/2tNQFB6>.

Dr Hall said the feedback from prescribing doctors "validated the chemistry of Nanabis which is distinct from hemp or medicinal cannabis".

Medlab was unchanged at 54.5 cents.

HAEMALOGIX

Haemalogix says it has a research collaboration with Tokyo's Takeda Pharmaceutical Co for the fatal blood cancer multiple myeloma.

Haemalogix said it that Takeda had two established treatments for multiple myeloma "marketed globally" and the pre-clinical research plan would build on its understanding of the prevalence and characteristics of its target antigens on the surface of malignant myeloma cells, which might be "an important target of new treatments for multiple myeloma in the future"

Last year, Haemalogix said it had acquired the research commercialization rights to an immuno-oncology agent for multiple myeloma (BD: Jul 31, 2017).

Haemalogix executive chairman Bryce Carmine told Biotech Daily at that time that his company had acquired the rights to a collaboration research undertaken by Sydney's Westmead Institute for Medical Research, Western Sydney Local Health District, Children's Medical Research Institute and the University of Sydney.

Mr Carmine said his company owned two antibodies to surface antigens only found on malignant cells and the research institutes had developed a chimeric antigen receptor T-cell from one of the antibodies.

Mr Carmine said that the cappa myeloma antigen was found only on malignant cells and the resultant immuno-oncology technology was designed to specifically target malignant cancer cells present in the bone marrow of multiple myeloma patients.

Mr Carmine said that the collaboration would confirm and characterize the target antigens and conduct research on new agents, which was expected to take up to two years.

Haemalogix said the financial terms of the collaboration would not be disclosed.

Haemalogix is a private company

CLINUVEL PHARMACEUTICALS

Lagoda Investment Manager, Fatima Dickey and Richard Bayles say they have reduced their holding in Clinuvel from 4,778,296 shares (10.01%) to 3,405,794 shares (7.12%). The New York-based Lagoda said it bought and sold shares on market between May 16 and July 2, 2018 at prices ranging from \$10.00 to \$13.13. Clinuvel was up 14 cents or 1.3 percent to \$11.00.

ALCIDION

In a series of announcements, Isle of Wight Pty Ltd, Colin MacKinnon, Donald Kennedy and the Caledonia Trust said they had become substantial in Alcidion.

In April, Alcidion said it would buy MKM Health and Patientrack for 198,000,000 shares, valued at \$10,000,000 or 5.05 cents a share, with \$2,000,000 payable in cash and with MKM chief executive officer Kate Quirke to be Alcidion chief executive officer and Ray Blight to continue as executive chairman (BD: April 24, 2018).

Today, Mr MacKinnon as director of Isle of Wight, the MacKinnon Superfund and MKMS, said he held 51,911,713 shares or 6.44 percent of Alcidion, buying 130,000 shares for \$5,876 or 4.5 cents a share on May 4, 2018 and receiving the balance of the shares on July 3, 2018 as non-cash consideration for the sale of shares in MKM Health and Patientrack Holdings.

Mr Kennedy said that as a director of Caledonian Nominees and MKMS, he held 51,781,713 shares or 6.43 percent of Alcidion, acquiring the shares on July 3, 2018 as non-cash consideration for the sale of shares in MKM Health and Patientrack Holdings. Alcidion was up 0.2 cents or four percent to 5.2 cents.

ALCIDION

Alcidion chairman Ray Blight says he has increased and been diluted in the company from 97,051,004 shares (16.10%) to 100,071,004 shares (12.42%).

Mr Blight said that between April 24 and 27, 2018 he bought 3,020,000 shares for \$129,172 or 4.3 cents a share and was diluted by the issue of shares for the purchase of MKM Health and Patientrack Holdings.

GENERA BIOSYSTEMS

Genera has requested a voluntary suspension to follow the trading halt requested on July 2, "pending an announcement ... regarding a proposed capital raising".

Separately on the same day, Genera said the capital raising was to re-finance its series B convertible notes (BD: Jul 2, 2018).

Genera last traded at 16 cents.

NUHEARA

Nuheara says that founder Dr Michael Ottaviano has resigned from the company as a non-executive director, effective today.

Nuheara chief executive officer Justin Miller said that the company thanked Dr Ottaviano "for his service as one of the company's founding directors".

"Dr Ottaviano played an important role during Nuheara's founding years and we now wish him well in his future endeavours," Mr Miller said.

Nuheara fell half a cent or 4.8 percent to 10 cents.

NEUREN PHARMACEUTICALS

Neuren says it has appointed Dianne Angus, Patrick Davies and Dr Jenny Harry as non-executive directors.

Neuren said the three brought “skills, diversity and experience in drug development and commercialization that are highly relevant to Neuren as a leading developer of new treatments for neurological disorders”.

The company said that the new six-member board would comprise four independent non-executive directors and two executive directors.

Neuren said that former Prana chief operating officer Ms Angus was currently the interim chief executive officer of the Victorian Australian Medical Association and was a registered patent and trademark attorney.

The company said that Mr Davies held executive management roles in the healthcare industry for more than 20 years, including Symbion and Ebos Group.

Neuren said that Dr Harry was currently Ondek chief executive officer and was previously Tyrian Diagnostics chief executive officer.

Neuren fell 14 cents or 4.95 percent to \$2.69.

NEUROTECH INTERNATIONAL

The Malta-based Neurotech says it has appointed Dr David Cantor as a non-executive director.

Neurotech said that Dr Cantor was a member of its scientific advisory board, had more than 40 years in the academic and clinical neuroscience sector and was currently the chief executive officer and clinical director of the Suwanee, Georgia-based Mind and Motion Developmental Centres of Georgia, which provided diagnostic and treatment services to children and adults with autism, attention deficit hyperactivity disorder, traumatic brain injury and sensory processing disorders.

The company said that Dr Cantor was also the chief executive officer and managing partner of software company Braindx.

Neurotech said that Dr Cantor was a member of neuroscientific association boards, “a prolific author of numerous journal articles and book contributions”.

The company said that Dr Cantor held a Bachelor of Arts from the University of Connecticut, and a Masters of Arts and a Doctor of Philosophy from the State University of New York (Stony Brook).

Neurotech fell one cent or 6.1 percent to 15.5 cents.