



# Biotech Daily

Monday February 18, 2019

*Daily news on ASX-listed biotechnology companies*

- \* **ASX UP, BIOTECH DOWN: IMMUTEP UP 7%; AIRXPANDERS DOWN 17.5%**
- \* **FEDERAL \$22m FOR EARLY STAGE RESEARCH**
- \* **CLARITY RAISES \$9m, OPEN FOR \$1m MORE**
- \* **EMERALD CLINICS RAISES \$2.5m FOR IPO**
- \* **PHARMAUST RIGHTS ISSUE TO RAISE \$2m**
- \* **NEUREN NNZ-2591 'EFFECTIVE FOR PHELAN-MCDERMID IN MICE'**
- \* **BIONOMICS UP 54% ON 'SIGNIFICANT' BNC210 PTSD BLOOD RESPONSE**
- \* **J&J LIFESCAN PAYS UNIVERSAL BIOSENSORS TEST STRIPS \$44m**
- \* **PHARMAUST, EPICHEM EXTEND DNDI CONTRACT**
- \* **SUDA EUROPEAN, CHINESE PATENTS FOR SUD-003, SUD-004**
- \* **PROTEOMICS TO RELEASE 3.9m ESCROW SHARES**
- \* **REVA REQUESTS CAPITAL RAISING TRADING HALT**
- \* **CANADA MARIJUANA CULTIVATION LICENCE FOR CRESO**
- \* **TELEX APPOINTS GABRIEL LIBERATORE GROUP COO**
- \* **INVITROCUE APPOINTS PROF ARIAL ZENG YI CONSULTANT**

## MARKET REPORT

The Australian stock market was up 0.39 percent on Monday February 18, 2019, with the ASX200 up 23.7 points to 6,089.8 points. Seven of the Biotech Daily Top 40 stocks were up, 24 fell, seven traded unchanged and two were untraded.

Immutep was the best, up 0.2 cents or 6.7 percent to 3.2 cents with 6.4 million shares traded. Clinuvel and Pro Medicus improved more than three percent; Impedimed rose 2.1 percent; both CSL and Kazia were up 1.1 percent; with Genetic Signatures, Optiscan and Resmed up by less than one percent.

Airxpanders led the falls, down 0.7 cents or 17.5 percent to 3.3 cents, with 2.1 million shares traded. Orthocell lost 10 percent; Benitec and Opthea fell more than seven percent; Avita shed 6.9 percent; Antisense and Cyclopharm were down more than five percent; Osprey, Patrys, Telix and Universal Biosensors fell more than four percent; Medical Developments and Proteomics were down more than three percent; Dimerix and LBT shed more than two percent; with Actinogen, Cochlear, Compumedics, Nanosonics, Polynovo, Prescient and Volpara down more than one percent.

## FEDERAL GOVERNMENT

The Federal Government says it will provide funding \$22.3 million to MTP Connect for early stage research leading to interventions, cures and treatments for major diseases. In a media release, the Federal Minister for Health Greg Hunt said the funds from the Medical Research Future Fund be used for the Biomedical Translation Bridge initiative, in partnership with Biocurate, combining the University of Melbourne and Monash University and the University of Queensland's commercialization arm Uniquist.

Mr Hunt said that successful projects would receive between \$200,000 and \$1,000,000 over a maximum of three years and the funds would be used for early stage research into arthritis, asthma, back pain, cancer, cardiovascular disease, chronic obstructive pulmonary disease, diabetes and mental health conditions.

The media release said MTP Connect would operate the Biomedical Translation Bridge initiative, with Uniquist and Biocurate recommending eligible ventures for funding.

MTP Connect chief executive officer Dr Dan Grant said the partners brought "decades of industry-based experience and an enviable track record in research translation to the program".

"By joining forces with Biocurate, Uniquist and [Flinders University's Medical Device Partnering Program] we've created a powerful partnership venture that brings national reach, industry capabilities and expertise and commercial know-how to the task of boosting translation of Australia's health-tech research," Dr Grant said.

"MTP Connect will also partner with the Bridge and Bridgetech programs from the Queensland University of Technology," Dr Grant said.

Uniquist chief executive officer Dr Dean Moss said that through its involvement with the Biomedical Translation Bridge program, it would "draw on... commercialization and drug discovery expertise to help develop Australian technologies to the stage where they can attract further capital and support, bridging the funding gap and giving the country's ground-breaking medical research the best opportunity to create change in the lives of people in Australia and around the world".

## CLARITY PHARMACEUTICALS

Clarity says it has raised \$8,965,960 from existing investors and has opened the offer to external investors to raise a further \$1,034,046 to take the total to \$10,000,006.

Clarity said it raised \$5,000,003 from Sydney cancer treatment company Genesiscare and a further \$3,965,957 in a rights issue to existing shareholders (BD: Sep 18, 2018).

The company said the money would fund further development of 64-copper or Cu-64 Sartate and copper-67 or Cu-67 Sartate, which were "highly-targeted [diagnostic and therapeutic] pharmaceuticals with increased specificity and in-vivo stability".

Clarity said that Cu-64 Sartate allowed for diagnostic positron emission tomography (PET) imaging, as well as the potential for personalized dosimetry, and Cu-67 Sartate was "a potential therapeutic product which could enable treatment for cancers that express the somatostatin receptor 2 (SSTR-2)".

The company said it began its first therapy trial in July 2018 using Sartate for the brain cancer meningioma, had reached the 50 percent recruitment target and the trial data would help expand other indications that express SSTR-2, such as neuroblastoma.

Clarity said the funds would assist development of a prostate specific membrane antigen (PSMA) targeting product for the diagnosis and treatment of prostate cancer and a Bombesin (BBN) product that targetted the gastrin-releasing peptide receptor, present in lung, ovarian, prostate and breast cancer.

Clarity is a public unlisted company.

## EMERALD CLINICS

The Perth-based Emerald Clinics says it has raised \$2.5 million in convertible notes ahead of a planned initial public offer, scheduled for April 2019.

In a media release, Emerald said it operated medical marijuana clinics in Sydney and Perth and the capital raising was supported by Canada's Canopy Growth Corp, Melbourne marijuana grower Cann Group and US-based cannabis investor CB1 Capital.

Emerald chairman Dr Stewart Washer told Biotech Daily that the convertible notes were set at a 20 percent discount to the price at the proposed initial public offer.

The company said that PAC Partners was the sole lead manager to the raisings.

Emerald is a public unlisted company.

## PHARMAUST

Pharmaust says it hopes to raise \$2,003,007 in a two-for-five, non-renounceable rights issue at 2.5 cents a share.

Pharmaust said that the record date for the rights issue would be February 21, with the offer opening on February 26 and closing on March 19, 2019.

The company said the funds would be used to complete expenditure related to phase I/II canine trials of monepantel and to meet offer expenses and if funds raised exceeded the \$500,000 minimum, they would be used to "progress towards a human clinical trial".

Pharmaust fell 0.9 cents or 18.75 percent to 3.9 cents with 3.4 million shares traded.

## NEUREN PHARMACEUTICALS

Neuren says that drug candidate NNZ-2591 shows "positive effects" for Phelan-McDermid syndrome, in mice.

Neuren said that the London-based contract research organization Genpharma Research Laboratories (Gen.ddi) tested NNZ-2591 in a SHANK3 knock-out mouse model.

The company said that Phelan-McDermid syndrome was "a rare genetic condition caused by a deletion or other change in the 22q13 region of chromosome 22, which includes the SHANK3 gene, or a mutation of the gene".

Neuren said that Phelan-McDermid syndrome was also known as 22q13 deletion syndrome and the SHANK3 gene coded for the shank3 protein, which supported the structure of synapses between nerve cells in the brain.

The company said there was no treatment for Phelan-McDermid syndrome, which presented as intellectual disability, delayed or absent speech, symptoms of autism, low muscle tone, motor delays and epilepsy.

Neuren said that when treated with NNZ-2591 for three weeks, the knock-out mice with disrupted SHANK3 genes had restored deficits in anxiety, repetitive behavior, motor performance and social interaction compared to normal mice, that treated mice had a 60 percent reduction in susceptibility to seizures and the abnormal length of dendrite spines between brain cells, the excess activated ERK protein and the depressed level of insulin-like growth factor-1 (IGF-1) were all normalized after NNZ-2591 treatment.

Neuren said it was investigating the effects of NNZ-2591 on other neuro-developmental disorders including autism.

Neuren executive chairman Dr Richard Treagus said the results were "highly encouraging, both for the potential to address the unmet need in Phelan-McDermid syndrome and reinforcement of our view that NNZ-2591 could have broad utility in neuro-developmental and autism spectrum disorders".

Neuren fell half a cent or 0.4 percent to \$1.325.

## BIONOMICS

Bionomics says that a drug exposure-response analysis shows a statistically significant response of BNC210 for post-traumatic stress disorder.

Last year, Bionomics said its 193-patient, phase II trial of the anti-anxiety drug BNC210 in adults with post-traumatic stress disorder (PTSD) failed to meet its primary endpoint of decrease in PTSD symptoms as measured by the clinician-administered PTSD scale for the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders, Fifth edition (DSM-5), or CAPS-5 at 12 weeks (BD: Oct 2, 2018).

The company said in October that "evidence of anti-depressant effects and anti-anxiety activity [was] observed in the CAPS-5 symptom clusters [and] BNC210 treatment was safe and well-tolerated".

Today, Bionomics said that an analysis of absorption of the liquid formulation as shown in blood samples, rather than the dose of the drug taken, was mapped against the CAPS-5 responses and found a statistically significant benefit over placebo ( $p < 0.01$ ).

Bionomics said the liquid formulation needed to be taken with high fat food and the company suspected that some patients had not complied with the requirement.

The company said it was developing "an improved solid dose formulation which [had] recently been evaluated in [six] healthy human volunteers" and would not have the food requirement.

Bionomics said that the new data provided by the Uppsala, Sweden-based Pharmetheus AB meant it would seek US Food and Drug Administration guidance on the next steps for BNC210 for PTSD including the design of a further trial and whether BNC210 was eligible for fast track and breakthrough designation.

The company said that data from the ongoing BNC210 trial for agitation would be analyzed by dose and by measures of exposure with the read-out expected by July, 2019. Bionomics executive chairman Dr Errol de Souza said that the results of "the complex and time-consuming drug exposure analyses were not available and could not have readily been foreseen".

"The results of the further analysis are meaningful for future development of BNC210 and they support its continued development for PTSD, as well as other indications, and our ongoing partnering activities," Dr De Souza said.

The company told a teleconference that while there was a dose response in the phase II trial for PTSD and the 600mg dose had the best response, it might not need to increase the dose for further trials with the new tablet formulation.

Dr de Souza said that the company was "pretty excited by these data".

He said that the right formulation and dose would help with partnering discussions.

Dr de Souza said there was an ongoing strategic review being conducted by Greenhill & Co and whether the company would consider conducting a second trial would have to wait until the review was completed.

He said that the company had more than \$27 million in cash at December 31, 2018.

Bionomics climbed 6.5 cents or 54.2 percent to 18.5 cents with 25.4 million shares traded.

## UNIVERSAL BIOSENSORS

Universal Biosensors says it has received \$US31,503,880 (\$A44,036,123.46) as a lump sum service fee from Johnson & Johnson's Lifescan.

Universal Biosensors said it received the lump sum service fee as a buy-out from Lifescan's obligation to pay quarterly service fees for its Verio blood sugar test strips and would not receive any further quarterly services fees (BD: Sep 26, 2018).

Universal Biosensors fell one cent or 4.2 percent to 23 cents.

## PHARMAUST

Pharmaust says its wholly owned subsidiary Epichem has extended its contract to provide chemistry expertise to the Drugs for Neglected Diseases Initiative until 2020.

Pharmaust said under the extended contract, Epichem would continue to provide synthetic and medicinal chemistry expertise to support the Initiative's drug discovery projects until December 31, 2019.

The company said it expected the contract extension to generate up to \$1.24 million in revenue for Epichem.

## SUDA PHARMACEUTICALS

Suda says the European and Chinese Intellectual Property Offices have accepted patent applications for its sildenafil-based products SUD-003 and SUD-004.

Suda said that both patents were titled 'Oral Spray Formulations and Methods for Administration of Sildenafil' and covered the administration of sildenafil, the active pharmaceutical ingredient in SUD-003 for erectile dysfunction and SUD-004 for the treatment of anti-depressant-induced erectile dysfunction and pulmonary arterial hypertension, until December 2032.

The company said it had similar patents granted in the US, Japan, Russia, Australia, New Zealand, Canada, Singapore and South Africa.

Suda was unchanged at 0.55 cents.

## PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says that 3,868,305 shares issued for the acquisition of 10 percent of CPR Pharma Services will be released from voluntary escrow on March 5, 2019.

Proteomics most recent Appendix 3B new share announcement said the company had 80,511,965 shares on issue, with no further shares in escrow.

Proteomics fell 1.5 cents or 3.85 percent to 37.5 cents.

## REVA MEDICAL

Reva has requested a trading halt pending "an accurate update on its capital raising efforts".

Trading will resume on February 20, 2019 or on an earlier announcement.

Reva last traded at 17 cents.

## CRESO PHARMA

Creso says that Canada has approved a licence to cultivate marijuana products at its Nova Scotia-based Mernova Medical facility.

Creso said the Health Canada licence allowed it to cultivate, sell and distribute dried and fresh cannabis, cannabis plants and cannabis plant seeds.

Creso was up half a cent or 1.3 percent to 39 cents with 1.6 million shares traded.

## TELIX PHARMACEUTICALS

Telix says it has appointed Gabriel Liberatore as group chief operating officer. Telix said Mr Libertore had 20 years of business development experience, including 12 years at CSL, three years at Deloitte Australia, three years at the Melbourne-based Swisse Wellness and most recently worked with Melbourne's PACT Group. The company said Mr Libertore held a Doctor of Philosophy from the University of Melbourne and a Master of Business Administration from La Trobe University. Telix fell three cents or 4.1 percent to 70 cents.

## INVITROCUE

Invitrocue says it has appointed Prof Arial Zeng Yi as a patient-derived organoid consultant. Invitrocue said Prof Zeng was the principal investigator at the Shanghai Institute of Biochemistry and Cell Biology and the Chinese Academy of Sciences. The company said Prof Zeng was an expert of mammary stem cell and breast cancer for regenerative and cancer medicine. Invitrocue said Prof Zeng held a Bachelor of Science and a Master of Science from the Guangzhou, China-based Jinan University and a Doctor of Philosophy from the Vancouver, British Columbia-based Simon Fraser University. Invitrocue was untraded at seven cents.