



Biotech Daily

Thursday December 12, 2019

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: NEUREN UP 8%; PARADIGM DOWN 12%**
- * **FEDERAL \$14.7m HORIZON, BRIDGE GRANTS FOR 17 PROJECTS**
- * **PRESCIENT: 1 PTX-200 OVARIAN CANCER PARTIAL RESPONSE; COSTS**
- * **WEHI, NIH LINK RIPK1 TO CRIA SYNDROME**
- * **RESAPP RECEIVES \$1.8m R&D TAX INCENTIVE**
- * **ANTISENSE REQUESTS ATL1102 DMD TRIAL RESULTS TRADING HALT**
- * **ELLEX EXTENDS LASER, ULTRASOUND BUSINESS SALE SUSPENSION**
- * **MEDLAB, CULTECH EXPAND ORSBIOTIC, NANOCBD IN UK**
- * **BOD, UNI OF SA RESEARCH 'EFFECT' OF MARIJUANA MEDICABILLIS**
- * **HOLISTA WATER SOLUBLE CBD MARIJUANA OIL**
- * **EMPERY TAX EFFICIENT REDUCES TO 6% OF BENITEC, IN 2018**

MARKET REPORT

The Australian stock market fell 0.65 percent on Thursday December 12, 2019, with the ASX200 down 43.8 points to 6,708.8 points. Seven of the Biotech Daily Top 40 stocks were up, 21 fell, seven traded unchanged and five were untraded.

Neuren was the best, up 18 cents or 7.8 percent to \$2.48, with 178,945 shares traded. Polynovo climbed 4.5 percent; LBT rose 2.9 percent; Amplia and Dimerix were up more than one percent; with Cochlear, Cynata and Opthea up by less than one percent.

Paradigm led the falls for the second day in a row, down 38 cents or 12.1 percent to \$2.75, with 2.9 million shares traded. Telix lost eight percent; Compumedics was down 6.4 percent; Genetic Signatures and Impedimed retreated more than five percent; Alterity, Next Science and Patrys fell more than four percent; Imugene, Kazia, Medical Developments, Osprey and Pro Medicus were down more than three percent; Actinogen, Clinuvel, Immutep, Prescient and Universal Biosensors shed more than two percent; CSL, Nanosonics and Starpharma were down more than one percent; with Mesoblast and Resmed down by less than one percent.

FEDERAL GOVERNMENT

The Federal Government says it will provide \$14.7 million in grants for 17 innovative medical projects.

A media release from Federal Health Minister Greg Hunt said the matched industry funding projects would be funded through the Medical Research Future Fund, including \$8.9 million for nine projects through the Biomedtech Horizons program and \$5.8 million for eight projects through the Biomedical Translation Bridge program.

The Government said the Horizon projects included Cyban's brain pulse oximeter to monitor brain oxygen levels following traumatic brain injury, Macuject's artificial intelligence clinical decision support software for management of age-related macular degeneration, Polyactiva's sustained release ocular implants to deliver steroids and non-steroidal anti-inflammatory medications for macular oedema and Enlighten Imaging's hyper-spectral retinal imaging platform for artificial intelligence diagnostics.

The media release said further Horizon projects included Kunovus Technologies' motion-preserving implant for lumbar spine osteoarthritis, IDE Group's control sleeve for intravitreal injection systems, Intellidesign's portable low field magnetic resonance imaging, Wearoptimo's cardiac micro-wearables for minimally-invasive personalized cardiovascular medicine, and Advanced Genetic Diagnostics' tests for heart disease.

The Government said the Biomedical Translation Bridge projects of up to \$1 million each included Adalta's I-body protein for idiopathic pulmonary fibrosis, DBS Technologies' device for Parkinson's disease deep brain stimulation, Mecrx's small molecule drugs for lung cancer, and the University of Melbourne's Dental School's dental implant.

The media release said further BTB projects included Australian National University's rapid and objective eye and brain testing for better management of ophthalmic and neurological diseases, Speedx's Resistance Plus test to identify bacterial infections related to cystic fibrosis, using gene markers to predict antibiotic susceptibility or resistance, Vast Bioscience's 3-D small molecule sodium channel inhibitors for postsurgical pain and Noisy Guts' non-invasive acoustic belt, which used artificial intelligence to decode gut noises and diagnose and monitor common gut disorders including irritable bowel syndrome.

PRESCIENT THERAPEUTICS

Prescient says one of 15 patients treated with PTX-200 for platinum resistant ovarian cancer had a partial response, with the company concerned about rising offshore costs.

Prescient said the patients were treated with 15 to 25 milligrams/metre square (mg/m²) PTX-200 in its 15-patient, phase Ib safety study, in order to find the maximum tolerated dose of PTX-200, in combination with carboplatin.

The company said interim data showed that 12 of 15 patients had disease control, 11 patients exhibited "stable disease", one patient had a partial response and three were unstated by the company.

Prescient said seven serious adverse events were reported, with a case of grade two vomiting resulting in hospitalization considered to be possibly related to PTX-200.

The company said it had not completed dose escalation and believed it had not found the optimal dose.

Prescient chief executive officer Steven Yatomi-Clark said that "in the interests of mitigating the rising costs of conducting clinical trials overseas, Prescient will seek to continue studying PTX-200 in ovarian cancer in Australia and/or as an investigator-sponsored study backed by non-dilutive funding".

Prescient fell 0.2 cents or 2.3 percent to 8.5 cents with 39.8 million shares traded.

[THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH](#)

The Walter and Eliza Hall Institute says cleavage-resistant RIPK1-induced auto-inflammatory syndrome is caused by a mutation in a critical cell death component. WEHI said its staff working with the US National Human Genome Research Institute at the National Institutes of Health discovered and identified the genetic cause of the previously unknown human autoinflammatory disease, which they termed cleavage-resistant RIPK1-induced autoinflammatory, or CRIA, syndrome, caused by a mutation in the critical cell death component RIPK1.

The Institute said the research team was led by its Dr Najoua Lalaoui and Prof John Silke, who collaborated with the National Human Genome Research Institute's Dr Steven Boyden, Dr Hirotsugu Oda and Dr Dan Kastner.

The research, titled 'Mutations that prevent caspase cleavage of RIPK1 cause autoinflammatory disease' was published in Nature and an abstract is available at:

<https://www.nature.com/articles/s41586-019-1828-5>.

WEHI said that the RIPK1 mutation led to "runaway inflammation and cell death" and the discovery suggested that compounds that inhibited cell death might be useful in treating autoinflammatory diseases.

Dr Lalaoui said that cell death pathways had developed "a series of inbuilt mechanisms that regulate inflammatory signals and cell death, because the alternative is so potentially hazardous".

"However, in this disease, the mutation in RIPK1 is overcoming all the normal checks and balances that exist, resulting in uncontrolled cell death and inflammation," Dr Lalaoui said.

The Institute said that autoinflammatory diseases were caused by abnormal activation of the innate immune system, leading to recurrent episodes of fever and inflammation that can damage vital organs.

WEHI said that the researchers described patients from three families with a history of episodic high fevers and painful swollen lymph nodes.

The Institute said the patients were diagnosed with CRIA syndrome and had other inflammatory symptoms which began in childhood and continued into their adult years.

Dr Boyden said the first clue that the disease was linked to cell death was when they investigated the patients' exomes, the part of the genome that encoded all of the proteins in the body.

"We sequenced the entire exome of each patient and discovered unique mutations in the exact same amino acid of RIPK1 in each of the three families," Dr Boyden said.

"It is remarkable, like lightning striking three times in the same place," Dr Boyden said.

"Each of the three mutations has the same result – it blocks cleavage of RIPK1 – which shows how important RIPK1 cleavage is in maintaining the normal function of the cell," Dr Boyden said.

Dr Lalaoui said Walter and Eliza Hall Institute researchers confirmed the link between the RIPK1 mutations and CRIA syndrome in laboratory models.

"We showed that mice with mutations in the same location in RIPK1 as in the CRIA syndrome patients had a similar exacerbation of inflammation," Dr Lalaoui said.

Dr Dan Kastner said the NIH team had treated CRIA syndrome patients with a number of anti-inflammatory medications, including high doses of corticosteroids and biologics, with some of the patients markedly improved on an interleukin-6 inhibitor, while others responded less well or had significant side effects.

"Understanding the molecular mechanism by which CRIA syndrome causes inflammation affords an opportunity to get right to the root of the problem," Dr Kastner said.

"The discovery of CRIA syndrome also suggests a possible role for RIPK1 in a broad spectrum of human illnesses, such as colitis, arthritis and psoriasis," Dr Kastner said.

RESAPP HEALTH

Resapp says it has received \$1,798,086 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Resapp said the rebate related to research and development expenditure for the year to June 30, 2019.

Resapp fell half a cent or two percent to 24 cents with one million shares traded.

ANTISENSE THERAPEUTICS

Antisense has requested a trading halt pending an announcement in relation to the preliminary results of [its] ATL1102 for Duchenne muscular dystrophy ... trial".

Last month, Antisense said it had completed dosing of its nine-patient, six-month, phase II trial of ATL1102 for Duchenne muscular dystrophy (BD: Nov 20, 2019).

Trading will resume on December 16, 2019 or on an earlier announcement.

Antisense last traded at 8.2 cents.

ELLEX MEDICAL LASERS

Ellex has requested a further extension to its suspension to continue negotiations "in relation to the proposed sale of Ellex's Lasers and Ultrasound business segment".

Last month, Ellex requested a voluntary suspension until December 12, 2019 to finalize the sale of the business segment, responsible for \$65,522,000 or 80.3 percent of total revenue for the year to June 30, 2019 (BD: Nov 28, 2019).

Today, the company said it expected the suspension to last until January 15, 2020 or on an earlier announcement.

Ellex last traded at 61 cents.

MEDLAB CLINICAL

Medlab says its UK partner Cultech will distribute its Orsbiotic probiotic rehydration formulation and cannabidiol (CBD) marijuana derivative, Nanocbd.

Medlab said the deal would provide "20 percent royalties ex-factory" and it expected both products to be online within the next three months.

Medlab was up 2.5 cents or 8.3 percent to 32.5 cents.

BOD AUSTRALIA

Bod says it will collaborate with the University of South Australia to research the effects of its Medicabillis medical marijuana on patients.

Bod said the unspecified research would be undertaken at the University's School of Pharmacy and Medical Science to assist ongoing product development initiatives and provide information for clinical practice and future research.

The company said it expected results by March 2020 and would then begin commercialization initiatives, but did not state specifically what the collaboration would study.

Bod fell one cent or 2.9 percent to 34 cents.

[HOLISTA COLLTECH](#)

Holista says it has filed a patent for its platform technology to deliver fat-soluble medications, including cannabidiol (CBD) oil, through a water-soluble delivery system. Holista said the technology would make CBD formulations up to 40 times better absorbed, allowing dosages to be reduced, and taste masking technology would increase acceptance in oral pharma and food formulations.

In what appears to be Holista's first announcement that it was adding marijuana to its low glycemic index sugars, pasta, breads and other foods, the company said the water soluble marijuana-derived oil would benefit the CBD oil industry, where active material was "scarce, costly and poorly water-soluble".

Holista said the patent was registered in the US for global coverage and it would focus on CBD, curcumin and Vitamin D to initially target Australia and North America.

The company said it had begun negotiations with North American CBD processing companies and expected to begin commercialization in North America in 2020.

Holista said it would charge companies an industry-standard formulation fee for non-exclusive access, followed by a quarterly licencing fee and royalties based on wholesale pricing.

Holista was up 0.6 cents or eight percent to 8.1 cents with 1.2 million shares traded.

[BENITEC BIOPHARMA](#)

Empery Tax Efficient says it has reduced its substantial shareholding in Benitec from 28,000,000 shares (8.94%) to 19,567,600 shares (6.09%).

The New York-based Empery said that it sold 8,432,400 shares on market on July 23, 2018, but failed to provide the value as required by the Corporations Act 2001.

In October, Empery said it became substantial in Benitec with 1,400,000 American depository shares, for \$US980,000, equivalent to 28,000,000 Australian shares at 5.2 cents a share (BD: Oct 7, 2019).

Benitec was unchanged at four cents.