Biotech Daily

Monday March 20, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ONCOSIL UP 21%; MICRO-X DOWN 9%**

*** VICTORIA: MONASH UNI, ISRAEL'S SHEBA MEDICAL R&D AGREEMENT**

*** LBT, LIND $1.5m DRAWN DOWN EQUITY FACILITY**

*** CLINUVEL STARTS PRENUMBRA ARTERIAL ISCHAEMIC STROKE TRIAL**

*** BIOXYNE TO BUY 83% OF BREATHE LIFE SCIENCES**

*** GERMANY APPROVES INVEX PRESENDIN IIH TRIAL**

*** EMYRIA HAS 150 MDMA ANALOGS**

*** SALTER BROTHERS TAKE 7% OF NUHEARA**

*** NEUROTECH MARIJUANA NTI164 RETT SYNDROME TRIAL**

MARKET REPORT

The Australian stock market fell 1.38 percent on Monday March 20, 2023, with the ASX200 down 96.3 points to 6,898.5 points. Seven of the Biotech Daily Top 40 stocks were up, 26 fell, five traded unchanged and two were untraded. All three Big Caps fell.

Friday's 54.8 percent worst, Oncosil, was today's best, up 0.3 cents or 21.4 percent to 1.7 cents, with 11.5 million shares traded. On Friday, Oncosil fell from 3.1 cents to 1.4 cents.

Nova Eye climbed 10 percent; Imugene and Universal Biosensors improved four percent or more; Impedimed and Polynovo were up more than one percent; with Next Science up by 0.7 percent.

Micro-X led the falls, down one cent or 9.1 percent to 10 cents, with 578,631 shares traded.

Prescient lost 8.3 percent; Kazia fell 7.1 percent; Emvision was down 6.8 percent; Antisense, Neuren and Starpharma were down more than five percent; Actinogen, Avita, Clinuvel and Patrys fell four percent or more; Compumedics, Opthea, Paradigm, Pro Medicus and Proteomics were down more than three percent; Genetic Signatures, Medical Developments, Mesoblast, Nanosonics, Resonance and Telix shed two percent or more; Cochlear, Cynata, Immutep, Orthocell, Resmed and Volpara were down more than one percent; with CSL down by 0.8 percent.

VICTORIA GOVERNMENT

Victoria says Monash University and Tel Aviv's Sheba Medical Center will research and develop healthcare models including to improve heart disease treatment.
A media release from Victoria's Minister for Industry and Innovation Ben Carroll said the State Government would invest about $200,000 with Monash University's Victorian Heart Institute to improve access to technology and enable faster adoption of new treatments for cardiovascular disease.
The media release said that the partnership would enhance healthcare delivery for the state and help create new jobs in medical technology research, manufacturing and export.
The Government said the agreement was "to research and develop more equitable healthcare models and [medical technology] manufacturing opportunities in Victoria".

LBT INNOVATIONS

LBT says New York's Lind Global Fund II will pay $1.5 million for $1.7 million in shares, to be issued over the next two years.
LBT said the subscription price would be the lesser of 9.2 cents each or 90 percent of the average of the three lowest volume-weighted average prices during the 20 days prior to the subscription.
The company said it could repay the facility in cash, but allowing Lind to subscribe for one third of the $1.7 million.
LBT said that Lind would be issued 7,500,000 options exercisable at five cents each with four years and pay a $60,000 "commitment fee".
The company said it would issue the 10,000,000 initial shares to Lind and if at the end of the term there were initial shares not subscribed or repaid, Lind would buy those shares at the subscription price.
LBT said the funds would be used to commercialize its Apas automated plate assessment system instruments, ahead of the finalization of its microbial quality control testing, expected in 2024, as well as support sales, sales team training and working capital.
LBT was unchanged at 4.5 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says it has dosed the first of 12-patients in its 42-day, phase II trial of Prenumbra Instant (afameltanotide) for arterial ischaemic stroke.
In July, Clinuvel said it would develop its subcutaneous liquid injectable Prenumbra Instant as a treatment for arterial ischaemic stroke, following a pilot study that had five of six patients show improved neurological functions after a 16mg dose (BD: Jul 28, 2022).
Today, the company said the trial would evaluate the safety and efficacy of afamelanotide therapy in arterial ischaemic stroke patients that were ineligible for the standard-of-care, including intravenous thrombolysis or endovascular thrombectomy.
Clinuvel said arterial ischaemic stroke was caused by and arterial clot blocking blood to the brain, and accounted for 85 percent of the 15 million strokes incurred globally each year, with about 70 percent to 80 percent of patients were ineligible for treatment by intravenous thrombolysis or endovascular thrombectomy.
The company said it would treat six patients suffering mild to moderate stroke and the other six suffering moderate to severe stroke.
Clinuvel said the first results were expected by the end of the year.
Clinuvel fell 93 cents or 4.6 percent to $19.39 with 92,264 shares traded.

BIOXYNE

Bioxyne says it will buy about 83 percent of the Gold Coast, Queensland-based Breathe Life Sciences and its subsidiaries, but did not disclose a price.
Bioxyne said Breathe Life Sciences operated in Australia, the UK, Japan and Europe and manufactured, sold and distributed plant-based products and supplements, including cannabidiol, marijuana extracts, vitamins, manuka honey, skin care products and mushroom extract products.
The company said the purchase was subject to shareholder approval and other conditions, with a shareholders' meeting expected to be held in May 2023.
Bioxyne fell 0.15 cents or 6.1 percent to 2.3 cents.

INVEX THERAPEUTICS

Invex says it has German approval for its 240-patient, phase III trail of Presendin for idiopathic intracranial hypertension (IIH).
In November, Invex said the first of 240 idiopathic intracranial hypertension patients had been randomized in the 24-week, randomized, placebo-controlled, double-blind trial, evaluating the safety and efficacy of Presendin (BD: Nov 21, 2022).
At that time, the company said that the primary endpoint was the change in intracranial pressure, with secondary endpoints of vision and headache outcomes.
In January, Invex said that it had opened its first US site at the Bellaire, Texas Eye Wellness Center (BD: Jan 22, 2023).
Today, Invex said the German approval was its "first national regulatory clearance in Europe for our study".
Invex was up one cent or 2.2 percent to 46 cents.

EMYRIA

Emyria says it has 150 novel analogs of 3,4 methylene-dioxy-meth-amphetamine (MDMA), in collaboration with the University of Western Australia.
Emyria said it hoped to use its MDMA analogs to develop a faster acting MDMA for post-traumatic stress disorder therapy, as well as a version of the drug without euphoria for Parkinson's patients being treated with levodopa.
The company said that, with the University of Western Australia, it had synthesized and shipped a fifth batch of 19 distinct compounds for a preliminary screening with Luxembourg's Eurofins.
Last year, Emyria said it had shipped its fourth batch to Eurofins and had 140 analogs at that time (BD: Oct 18, 2022).
Emyria said it had exclusive rights to all MDMA-like compounds created in the partnership with the University of Western Australia.
Emyria fell 2.5 cents or 12.8 percent to 17 cents with one million shares traded.

NUHEARA

Salter Brothers Emerging Companies says it has increased its substantial holding in Nuheara from 8,655,556 shares (5.62%) to 11,941,176 shares (6.96%).
Melbourne's Salter Brothers said that between December 31, 2022 and March 14, 2023 it bought 3,285,620 shares for $572,492 or an average of 17.4 cents a share.
Nuheara was unchanged at 17 cents.

NEUROTECH INTERNATIONAL

Neurotech says it will conduct a 15-patient, phase II trial of its daily, oral, marijuana-based NTI164 for the genetic illness Rett syndrome.

Neurotech said it would file an ethics application for the trial to be conducted at Melbourne's Royal Children's Hospital with co-principal investigator Dr Giuliana Antolovich and at Melbourne's Monash Medical Centre with co-principal investigator Prof Michael Fahey, with approvals expected by July, the trial to begin this year and initial by July 2024.

The company said that Rett syndrome was "a rare genetic neurological and developmental disorder and is almost exclusively the result of a mutation(s) in the methyl CpG binding protein 2 (MECP2) gene located on the X-chromosome, which is required for normal brain development and function, affecting one in 10,000 female live births.

Last week, Neurotech claimed statistically significant results from its 11-child phase I/II trial of marijuana-based low tetrahydrocannabinol and combination cannabidiol NTI164 for improving the symptoms associated with autism spectrum disorder over 52 weeks of treatment (BD: Mar 20. 2023).

During the week, Neuren climbed 72.5 percent to $13.23 on news that its North America partner Acadia Pharmaceuticals had US Food and Drug Administration approval for Daybue, or trofinetide, for the genetic illness, Rett syndrome (BD: Mar 13, 2023).

Today, Neurotech executive director Dr Thomas Duthy said that "the neuroprotection shown by NTI164 with improvements in neuronal function and strong anti-inflammatory effects in brain-derived neuronal and microglial cells could translate to improved clinical outcomes in Rett syndrome patients".

"When overlaid with NTI164's excellent safety profile, this new clinical focus in Rett syndrome where only one recently approved therapy now exists and the global market potentially worth over $US2 billion annually, will allow Neurotech to further diversify its clinical pipeline and drive shareholder value," Dr Duthy said.

Neurotech said that the proposed primary endpoints at 12 weeks of treatment were the Rett syndrome behavior questionnaire (RSBQ), the clinical global impression scale-improvement (CGI-I) and the CGI-severity of illness (CGI-S).

The company said that secondary endpoints included safety, adverse events and measures associated with hand function, motor skills, communication and quality of life, along with biomarkers analyses.

Neurotech said that if the trial was successful, it would conduct a 14-week double-blind, randomized, placebo-controlled phase II in 34 participants to determine further efficacy and safety.

Neurotech fell 0.4 cents or 6.9 percent to 5.4 cents.