Biotech Daily

Tuesday August 6, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: AMPLIA UP 50%;**
- UNIVERSAL BIOSENSORS DOWN 16%

*** COMPUMEDICS WINS $1m GERMAN OKTI EEG DEAL**

*** AMPLIA FURTHER PANCREATIC PATIENT RESPONSE TO NARMAFOTINIB**

*** BURNET SELECTS 2 BURNEXT LIVER PROJECTS**

*** NYRADA COMPLETES NYR-BIO3 BRAIN INJURY RAT STUDY**

*** BLINKLAB, MONASH STUDY KETAMINE COGNITION TEST**

*** CLINUVEL APPOINTS CLAIRE NEWSTEAD-SINCLAIR CO SEC**

MARKET REPORT

The Australian stock market recovered 0.41 percent on Tuesday August 6, 2024, with the ASX200 up 31.0 points to 7,680.6 points.

Nineteen of the Biotech Daily Top 40 companies were up, 16 were down and five traded unchanged. All three Big Caps were up.

Amplia was the best, up 4.5 cents or 50.0 percent to 13.5 cents, with 6.1 million shares traded.

Curvebeam climbed 19.4 percent; Percheron was up 10.45 percent; Alcidion improved 9.2 percent; Dimerix was up eight percent; Clarity climbed 7.2 percent; Opthea was up 4.9 percent; Emvision and Proteomics were up three percent or more; Mesoblast, Paradigm, Resmed, Starpharma and Telix rose more than two percent; Aroa and Resonance were up more than one percent; with Avita, Clinuvel, Cochlear, CSL, Neuren and Polynovo up by less than one percent.

Universal Biosensors led the falls, down 1.5 cents or 11.1 percent to 12 cents, with 195,801 shares traded. Medadvisor, Medical Developments and Pro Medicus lost six percent or more; Actinogen and Syntara fell three percent or more; Cynata, Genetic Signatures, Imugene, Micro-X and Orthocell shed two percent or more; Cyclopharm, Immutep, Impedimed and SDI lost more than one percent; with Nanosonics down by 0.7 percent.

COMPUMEDICS

Compumedics says it has signed a $1 million (EUR600,00) deal with two, unnamed "significant epilepsy hospitals Berlin" for its Okti electro-encephalogram amplifier.
Compumedics said the contracts were sales of its Okti high-definition, portable electro-encephalogram (EEG) amplifier with interchangeable modules that allowed the recording of up to 128 channels of standard clinical montage and high-density EEG with one device.
The company said Okti provided "clinicians the confidence they need to ensure precision signal data acquisition, with accuracy underscoring clinical insights necessary to deliver the best possible healthcare outcomes".
Compumedics said Okti used its Nexus 360 internet cloud software, and was selected by Europe sites because it was "recognized for providing the most comprehensive and innovative premium, quality solution for ambulatory long-term video EEG".
The company said sales orders for the year to June 30, 2024 in Europe had increased 63 percent to $7.6 million due to "key sales in France to [Centre Hospitalier Universitaire] Angers and [Centre Hospitalier Universitaire] Amiens Picardie".
Compumedics said the sales would enable its French business to become "one of the most important vendors in the field of paediatric neurology in France".
The company said that in the year to June 30, 2024 it had completed sales in Germany to the Department of Neurology and the Berlin Institute of Health at the Berlin University of Medicine Charité (Berlin Institute of Health, Charité– Universitätsmedizin Berlin).
Compumedics said the Berlin Institute of Health had been awarded the contract "as part of a long, thorough, two-year selection process, involving a consortium incorporating five of the largest epilepsy centres in East Germany [including] Greifswald, Charité, Dresden, and Kleinwachau together with [several] health insurance companies".
The company said it had opened an innovation fund with the consortium to validate diagnosis into neurological care and reimbursement for ambulatory long-term video electro-encephalogram using its Okti device.
Compumedics was unchanged at 29.5 cents.

AMPLIA THERAPEUTICS

Amplia says an additional patient has had a confirmed partial response in its up-to 50-patient, phase IIa trial of narmafotinib, or amp945, for advanced pancreatic cancer.
Earlier this year, Amplia said it had dosed the first of up-to 50 patients in the trial of narmafotinib with chemotherapy for pancreatic cancer; and later, said it had enrolled all 26 patients in the first stage of the two-stage trial (BD: Jan 21, Jul 3, 2024).
Last month, the company said three of six patients in the trial had "recorded a confirmed partial response" (BD: Jul 25, 2024).
At that time, Amplia said that once six patients had confirmed partial or complete responses an additional 24 patients would be enrolled, for a total of 50 patients in the trial.
Today, the company said that "only a further two confirmed responses, [either] partial or complete, are required for the trial's interim analysis to support recruitment of the additional 24 patients in the second cohort of the trial".
Amplia said a partial response meant there was at least a 30 percent decrease in the overall size of tumor lesions, with no additional tumor lesions, sustained for two months; while a complete response was the total absence of tumor lesions for two months.
Amplia managing-director Dr Chris Burns said the activity of narmafotinib continued "to be very positive, consistent with our previous clinical and preclinical data".
"We remain on track to complete the interim analysis by the end of this quarter," he said.
Amplia was up 4.5 cents or 50 percent to 13.5 cents with 6.1 million shares traded.

BURNET INSTITUTE

The Burnet Institute says its Burnext accelerator program has invested its funding into two projects to develop an alanine transaminase (ALT) test and expand hepatitis C testing.
Earlier this year, Melbourne's Burnet Institute said it was investing an initial $6.5 million in the Burnext accelerator "to fast-track research into real-world outcomes to improve human health" (BD: May 10, 2024).
Today, the Institute said the two projects would cost $4 million over 24 months, with additional projects to be included as capacity expands.
The Burnet Institute said the target of the first project was a point-of-care test for alanine transaminase, which might indicate liver injury, possibly from drug reactions.
The Burnet said that the ALT finger-prick, point-of-care blood test was led by research translation scientific director Prof Heidi Drummer and research scientist Dr Lilian Hor.
The Institute said the wider availability of an ALT test would "mean that people undergoing clinical trials can monitor their liver health to ensure they remain healthy".
The Burnet Institute said the second project would expand access for hepatitis C testing and treatment through community pharmacies, with the program led by disease elimination deputy program director Prof Joe Doyle, who hoped to conduct more than 1,800 tests to identify up-to 600 individuals with hepatitis C.
Prof Doyle said the program would use the Insti hepatitis C blood test, but the program was about the model-of-care, rather than the test.
The Burnet Institute said the program would "establish a sustainable model for pharmacies to offer testing and treatment for other communicable diseases, thereby strengthening the link between community pharmacies and primary healthcare services".
The Institute's research translation office director Jennifer Barnes said "to meet the fund's objectives, the projects that were chosen had clear commercial or translational outcomes in line with our Burnet 2030 strategy and include significant milestones achievable within 24 months".
"To support the next phase of Burnext and the development of project plans, we are expanding the Institute's capability and resources, including recruiting new key positions for the Burnext portfolio," Ms Barnes said. "This is an exciting milestone."
Further information is available at: https://www.burnet.edu.au/technologies/burnext/.

NYRADA INC

Nyrada says it has completed its third of nine pre-clinical studies of NYR-BIO3 for brain injury, which have all supported the "safety and tolerability" of its drug candidate.
Earlier this year, Nyrada said two studies of NYR-BIO3 for brain injury had shown safety in-vitro, and "a significant neuro-protective signal", in mice (BD: Feb 28; July 16, 2024).
Today, the company said the third study showed that NYR-BIO3 was safe and tolerable in a "modified Irwin rat central nervous system test".
Nyrada said the test was a method used to study how a drug impacted the central nervous system, in which "researchers observe and record any changes in behavior, movements or activity levels … [to] determine if the drug causes any side effects related to the brain and nervous system, ensuring the drug's safety for further development".
The company said that subject to satisfactory completion of all the studies it would submit an ethics application for a first in-human, phase I trial before the end of 2024.
Nyrada said magnetic resonance imaging analysis had begun at the University of New South Wales for its separate pre-clinical traumatic brain injury study with the Walter Reed Army Institute of Research.
Nyrada fell 0.2 cents or 4.4 percent to 4.3 cents with 1.1 million shares traded.

BLINKLAB

Blinklab says with Melbourne's Monash University it will conduct a 35-volunteer study of its artificial intelligence-based test for monitoring the effects of ketamine on cognition.
Blinklab said the study would evaluate its medical device's ability to monitor the therapeutic effects of ketamine on cognitive processes "whereby sensory information is converted into decision making".
The company said the study would investigate "the impact of glutamate challenge on perceptual decision making, including behavioral performance, sensori-motor gating, by administering ketamine while participants perform a pre-pulse inhibition test using [the] Blinklab application".
Blinklab said the study would be conducted with Monash University's School of Psychological Sciences and hoped to show "whether administration of ketamine can disrupt basic sensory encoding mechanisms, will be detectable in reduced pre-pulse inhibition".
The company said the results from the study may help cognitive behavioral therapy outcomes in patients with psychiatric conditions such as depression, schizophrenia, epilepsy and post-traumatic stress disorder.
Blinklab said the participants would be 18-to-55 years of age and would complete three testing sessions after ketamine dosing, each, with participation expected to take four-to-five weeks per participant.
The company said it would provide the technology and data, with no financial obligation, and that each party would retain the rights and interest to its intellectual property.
Blinklab was unchanged at 24 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says it has appointed Claire Newstead-Sinclair as its company secretary, replacing interim company secretary Peter Vaughan, effective from today.
Earlier this year, Clinuvel said Mr Vaughan had replaced Darren Keamy as chief financial officer and been appointed as interim company secretary until August 6, when a permanent company secretary was expected to start (BD: Apr 15; Jun 28, 2024).
Today, the company said Ms Newstead-Sinclair had worked as chief financial officer and, or company secretary for Vistra Australia, Paragon Care, Invion, Mithril Resources, Far Ltd as well as Cogstate.
Clinuvel said Ms Newstead-Sinclair held a Bachelor of Business from Melbourne's Monash University.
Clinuvel was up six cents or 0.4 percent to $13.73.