



Biotech Daily

Tuesday September 17, 2024

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH EVEN: PERCHERON UP 8%; AMPLIA DOWN 10%**
- * **SYNCHRON IMPLANT PATIENT OPERATES AMAZON ALEXA**
- * **QUEENSLAND UNI DEVELOPS 'BELS' STROKE BEDSIDE TEST**
- * **QBIOTICS TIGILANOL TIGLATE 'SAFE, POSSIBLE SARCOMA EFFICACY'**
- * **BRANDON: W.H.O. GRANTS CERTA FT011 'ASENGEPRAST' NAME**
- * **OPYL'S TRIALKEY FOR ALITHIA TRIALS**
- * **MEMPHASYS \$500k KEYSTONEGROUP LOAN; CAPITAL RAISING**
- * **PHARMAUST APPLIES FOR MONEPANTEL MND EURO ORPHAN STATUS**
- * **NOXOPHARM COMPLETES SOF-SKN FORMULATION**
- * **GENETIC TECHNOLOGIES SUSPENDED: 'NOT MEETING RIGHTS MINIMUM'**
- * **ARGENICA APPOINTS PROF MARK ETHERTON, ROB BLACK DIRECTORS**

MARKET REPORT

The Australian stock market was up 0.24 percent on Tuesday September 17, 2024, with the ASX200 up 19.3 points to 8,140.9 points. Fifteen of the Biotech Daily Top 40 companies were up, 14 fell, 10 traded unchanged and one was untraded.

Percheron was the best, up 0.8 cents or 8.25 percent to 10.5 cents, with four million shares traded. Polynovo climbed 6.5 percent; Paradigm improved four percent; Compumedics, Curvebeam, Pro Medicus, Resonance and Telix were up more than three percent; Medical Developments and Nova Eye rose more than two percent; Cyclopharm and Resmed were up more than one percent; with Clarity, Clinuvel, Mesoblast and Nanosonics up by less than one percent.

Amplia led the falls, down 1.1 cents or 10 percent to 9.9 cents, with 376,964 shares traded. Atomo lost five percent; Alcidion, Immutep and Imugene fell four percent or more; Avita, SDI and Syntara shed two percent or more; Aroa, Cochlear, Emvision, Medadvisor, Opthea, Orthocell and Starpharma were down more than one percent; with CSL down by 0.2 percent.

[SYNCHRON](#)

Synchron says that, for the first time, one of its Synchron Switch brain implant patients has successfully operated an Amazon Alexa voice-assisted technology.

In 2022, the Melbourne and New York-based Synchron said it had raised \$110 million to accelerate development of its Synchron Switch platform product, a brain-implanted computer interface (BD: Dec 16, 2022).

Today, the company said the 64-year-old amyotrophic lateral sclerosis (motor neuron disease) patient used the Synchron brain computer interface to select customized tiles that performed pre-set Alexa actions “entirely hands and voice-free”, including turning lights on and off, making video calls, playing music and shows, controlling smart home devices, reading books on Kindle and purchasing items on Amazon.

Synchron said the integration of its technology with Alexa’s capabilities could allow users to control environments “inside and outside their homes” making every day routines more accessible and enhancing independence for those with severe paralysis.

The company said it aimed to expand the possibilities for smart home automation, enabling patients to use their thoughts to interact with a wide range of Alexa-compatible devices, from lights and plugs to thermostats and cameras, without the need for voice or physical interaction with a touch-screen.

Synchron said its device was “implanted in the blood vessel on the surface of the motor cortex of the brain via the jugular vein, through a minimally-invasive endovascular procedure”.

The company said that “once implanted, it is designed to detect and wirelessly transmit motor intent out of the brain, intended to restore the capability for severely paralyzed people to control personal devices with hands-free point-and-click”.

Synchron is a private company.

[THE UNIVERSITY OF QUEENSLAND](#)

The University of Queensland says it has developed a 20-to-30-minute bedside test that can detect often-missed rehabilitation needs for stroke patients.

The University of Queensland’s Prof Gail Robinson said that the ‘brief executive language screening’ (Bels) test assessed tested memory, motor function for speech, core language, conversational speech and complex mental abilities related to decision-making.

“Conventional testing for impairments following a stroke can take two to three hours, or most brief screens only detect severe impairments,” Prof Robinson said.

“Bels is a short, sensitive bedside test that only takes 20 to 30 minutes but is comprehensive and suitable for all stroke patients,” Prof Robinson said.

“It tests memory, motor function for speech, core language, conversational speech and complex mental abilities needed for decision making,” Prof Robinson said.

“Bels picks up subtle impairments in conversational speech and complex mental abilities that can be impacted by stroke but are often overlooked in patients who do not have obvious language problems that affect their ability to speak,” Prof Robinson said.

“If these impairments aren’t identified in hospital, patients can return home and find relationships, managing daily tasks or returning to work a challenge,” Prof Robinson said.

“Once a person is home, they’re also less likely to seek help, even when these subtle or hidden impairments affect their quality of life,” Prof Robinson said.

The University said that its researchers studied 88 stroke patients within seven weeks of their stroke, comparing their test results with 116 age-matched healthy individuals.

The University of Queensland said that it was developing a Bels test to assess the cognitive skills of people with brain tumors and dementia.

QBIOTICS

Qbiotics says preliminary data from an 11-patient phase IIa trial in soft tissue sarcoma shows tigilanol tiglate is safe, as well as 'early indications of efficacy'.

Qbiotics said data from the open-label trial was presented in a poster at the European Society for Medical Oncology, in Barcelona, Spain, September 13 to 17, 2024.

The company said that tigilanol tiglate aimed to induce tumor cell death and tumor vascular disruption, and was well-tolerated in its phase I dose-escalation study.

Qbiotics said clinical activity was observed in nine tumor types, and one angio-sarcoma patient had a "complete response" 43 days after a single injection and was "disease free" at 25 months post-injection.

The company said the primary endpoint was ablation rate, or the proportion of patients with a 30 percent or more reduction in tumor volume, with the secondary endpoints assessing safety and tolerability, with final results expected early in 2025.

Qbiotics is a public-unlisted company.

BRANDON CAPITAL, CERTA THERAPEUTICS

Brandon Capital says the World Health Organisation has granted Certa Therapeutics' fibrosis candidate FT011 the generic name "asengeprast".

Brandon said FT011 targeted GPR68 (G-protein coupled receptor 1), a membrane GPCR (G protein-coupled receptor) that was currently untreated and a "master switch of fibrosis".

The company said FT011 had "promising efficacy in multiple in-vitro and in-vivo models of inflammatory and fibrotic disease" and phase I and phase IIa studies in patients with systemic sclerosis had shown "favorable efficacy, safety and pharmaco-kinetics".

Certa chief executive officer Prof Darren Kelly said the World Health Organisation international non-proprietary name for asengeprast was an "important step in its development of this important therapy and follows the granting of EU and US orphan drug status and [a US Food and Drug Administration] fast track designation".

Brandon said Certa was planning for a phase IIb confirmatory systemic sclerosis trial.

Brandon Capital is a private company.

OPYL

Opyl says that Melbourne's Alithia Life Sciences will use Opyl's Trialkey data platform "to enhance clinical trial projects".

Opyl said Alithia was a contract research organization and would use its artificial intelligence analytics to provide data-backed insights for clinical trial design and planning. The company said Trialkey used bio-statistical validation, which was "capable of analyzing large datasets to generate optimized trial designs ... [and] provided "a comprehensive range of insights, including success probability predictions, optimal patient recruitment strategies and site selection recommendations".

The company said that Trialkey analyzed competitor assessments, allowing sponsors to understand how their trial variables compared within other companies; and the reports covered inclusion and exclusion criteria, sample size, study duration and endpoint determination, enabling researchers to refine trial protocols for better outcomes.

The company said the non-exclusive partnership would involve Alithia using Trialkey's reports to improve the efficiency and quality of their trial projects.

Opyl said it would receive \$5,000 or more for each report for a trial, but Alithia did not disclose the number of trials it ran each year.

Opyl was up 0.3 cents or 21.4 percent to 1.7 cents.

MEMPHASYS

Memphasys says it has a \$500,000, short-term, fixed return loan from the Perth-based Keystonegroup Investments Pty Ltd, ahead of a planned \$2 million capital raising.

Memphasys said the facility provided working capital for its commercialization projects as it awaited extraordinary general meeting approval of a \$2 million placement.

Last week, the company said it had 'commitments' to raise \$1.0 million in a placement at 0.8 cents a share and hoped to raise \$1.0 million in a share plan, with each share bought coming with one option exercisable at 1.1 cents within two years (BD: Sep 12, 2024).

Today, Memphasys said the loan terms included a fixed return of shares to the value of \$50,000 with free attaching options, in-line with its capital raising.

The company said the loan was repayable within 48 hours of a payment demand, which would be either after the general meeting ratifying the placement or on October 30, 2024, whichever came earlier.

Memphasys was up 0.1 cents or 12.5 percent to 0.9 cents.

PHARMAUST

Pharmaust says it has submitted a request to the European Medicines Agency for orphan medicinal product designation for monepantel for motor neuron disease.

Pharmaust said that, if granted, the designation would provide it with "significant regulatory support and commercial benefits", including 10 years post-authorization market exclusivity in the European Union.

The company said the submission was made following a meeting in August 2024 with the European Medicines Agency and the Committee for Orphan Medicinal Products.

In May, Pharmaust said the US Food and Drug Administration had granted orphan drug designation to monepantel as a treatment for motor neuron disease (MND) also known as amyotrophic lateral sclerosis (ALS) (BD: May 17, 2024).

Pharmaust was unchanged at 17 cents with 1.4 million shares traded.

NOXOPHARM

Noxopharm says it has completed development of its SOF-SKN topical lupus medication for its auto-immune disease trial.

In May, Noxopharm said it would increase production of its SOF-SKN for lupus to the standards required for regulatory submissions, increasing manufacturing 100-fold, and the drug would be used for regulatory safety studies (BD: May 14, 2024).

Today, the company said the formulation, which contained a proprietary ultra-short oligonucleotide that bound to inflammation sensors, released into the skin in a consistent manner and could deliver sustained concentrations for 48 hours.

Noxopharm was unchanged at 10 cents.

GENETIC TECHNOLOGIES

The ASX says it has suspended Genetic Technologies GTGN shares for not meeting "the minimum subscription condition under the non-renounceable entitlement offer".

Last week, Genetic Technologies said its rights offer at four cents a share raised \$324,648, leaving a \$3,553,145 shortfall (BD: Sep 12, 2024).

In July, Genetic Technologies said it hoped to raise \$3.85 million in a rights offer at four cents, with one option for every share issued (BD: Jul 26, 2024).

Genetic Technologies was unchanged at 3.9 cents.

ARGENICA THERAPEUTICS

Argenica says it has appointed Prof Mark Etherton and Rob Black as non-executive directors, effective from today.

Argenica said Prof Etherton had worked as chief resident and director at Massachusetts General Hospital and Brigham and Women's Hospital, was a professor at Harvard Medical School, and medical director at Biogen Inc and Takeda Pharmaceuticals.

The company said Prof Etherton held Doctor of Medicine and Doctorate of Philosophy from Austin's University of Texas.

Argenica said Mr Black had been a stockbroker in London, Sydney and Melbourne, and head of equity capital markets at Perth's Euroz Securities, and was chair of Carnavon Energy.

According to his LinkedIn page, Mr Black held a Bachelor of Business from Perth's Edith Cowan University.

Argenica was up 1.5 cents or 1.85 percent to 82.5 cents.