Biotech Daily

Wednesday July 17, 2024

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: ACTINOGEN UP 13%; SYNTARA DOWN 13%**

*** DE MOTU CORDIS DEVELOPS INHALED DMC-IH1 FOR ANAPHYLAXIS**

*** ALCIDION WINS $4m MIYA FOR HUME RURAL HEALTH DEAL**

*** CSIRO: 'BASAL FOREBRAIN ATROPHY MAY INDICATE ALZHEIMER'S'**

*** ALTERITY 'ATH434 IMPROVES LIFE IN 3 OF 7 MSA PATIENTS'**

*** PYC 1st VP-001 RP11 MULTIPLE DOSE TRIAL COHORT**

*** IMMUTEP PHASE I IMP761 AUTO-IMMUNE STUDY APPROVED**

*** NEXT SCIENCE TAKES $7.4m TIGA/THORNEY LOAN**

*** IMAGION REDUCES MERCER DRAW-DOWN FLOOR PRICE 92%**

*** IMRICOR REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** INSIGNIA TAKES 10.3% OF BOTANIX**

*** ALLEGRA DIRECTOR DR NICHOLAS HARTNELL TAKES 60%**

MARKET REPORT

The Australian stock market rose 0.73 percent on Wednesday July 17, 2024, with the ASX200 up 58.6 points to 8,057.9 points. Eighteen of the Biotech Daily Top 40 were up, 17 were down, three traded unchanged and two were untraded. All three Big Caps rose.

Actinogen was the best, up one cent or 13.0 percent to 8.7 cents, with 21.55 million shares traded. Polynovo climbed 9.3 percent; Next Science was up 8.0 percent; Prescient rose 7.5 percent; Curvebeam climbed 6.4 percent; Avita, Dimerix and Neuren improved more than five percent; Compumedics was up 3.2 percent; 4D Medical, Cynata and Genetic Signatures rose two percent or more; Cochlear, Cyclopharm, Medadvisor and Paradigm were up more than one percent; with Clarity, CSL, Micro-X, Resmed and Telix up by less than one percent.

Syntara led the falls, down 0.6 cents or 13.0 percent to four cents, with 4.4 million shares traded. Alcidion, Nova Eye and Orthocell lost more than five percent; Amplia and Mesoblast fell more than four percent; Atomo and Starpharma were down three percent or more; Nanosonics and Proteomics shed more than two percent; Emvision, Immutep, Impedimed, Medical Developments and Percheron fell more than one percent; with Clinuvel and Pro Medicus down by less than one percent.

DE MOTU CORDIS

Brisbane's De Motu Cordis (DMC) says it has appointed Catalant Pharma Solutions to manufacture its DMC-IH1 inhaled epinephrine for anaphylaxis.

A media release from De Motu Cordis said the company was founded in Brisbane, by the Critical Care Research Group and Bivacor founder Prof John Fraser.

The company said it was developing an inhaled epinephrine drug-device combination product for the treatment of anaphylaxis using a dry powder inhaler.

De Motu Cordis said the inhaler was "designed specifically for indications within emergency medicine in the community setting" and in a phase I trial outperformed injected formulations.

According to its website, the phase I studies showed that inhalation delivery of its epinephrine formulation was "eight times faster compared to a widely used autoinjector" for reaching plasma epinephrine maximum concentrations.

The company said with the Somerset, New Jersey-based contract development and manufacturing organization Catalent it would expand manufacturing of its device at Catalent's Boston, Morrisville and San Diego sites.

De Motu Cordis said the expanded manufacturing plans built on an original partnership with Catalent which began in November 2022.

According to the De Motu Cordis' website, its founder Prof Fraser was its chief medical officer, its chair was John Eales and its directors included Acrux chair Ross Dobinson.

According to Wikipedia, 'Exercitatio Anatomica de Motu Cordis et Sanguinis in Animalibus' (Latin for 'An Anatomical Exercise on the Motion of the Heart and Blood in Living Beings'), commonly called De Motu Cordis, was the best-known work of William Harvey published in 1628 establishing the circulation of blood.

De Motu Cordis chief executive officer Peter O'Neill said that Catalent was "one of the world's leading [contract development and manufacturing organizations]".

Mr O'Neill said the company looked "forward to Catalent's team supporting our ability to further advance DMC-IH1, through support for drug product manufacture and dry powder inhaler assembly".

"Catalent provides DMC with a consistency of quality and manufacturing excellence in the United States to service global markets," Mr O'Neill said.

The company said that it had raised more than $31m in seed rounds primarily in Australia, with the majority of funding via the Queensland Business Development Fund, high net worth individuals and Australian family offices.

De Motu Cordis said that a series A financing round was planned by July 2025, which would "ideally be anchored by a US based [venture capital firm]".

De Motu Cordis is a private company.

ALCIDION GROUP

Alcidion says it has signed a $4 million, five-year deal with Hume Rural Health Alliance to use its Miya Precision patient management and virtual care software.

Alcidion said the majority of the contract's total value would be "recognized as annual subscription revenue".

The company said it won the contract following a "detailed market analysis" by the Shepparton, Victoria-based Hume Rural Health Alliance, as well as independent advice.

Alcidion said the implementation and use of its Miya Precision technology would "increase visibility of bed availability across the region anticipated to lead to increased efficiency in bed management and better patient throughput".

Alcidion fell 0.3 cents or 5.1 percent to 5.6 cents with 4.6 million shares traded.

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The CSIRO says a study of data from 475 cognitively impaired people shows that "the atrophying of the basal forebrain" could indicate Alzheimer's disease.

The CSIRO said researchers studied the connection between the level of amyloid plaques in the brain, the atrophying or shrinking of the basal forebrain and a person's cognitive decline, including memory and attention, using data from the Australian Imaging, Biomarkers and Lifestyle, a consortium of Austin Health, the CSIRO, Perth's Edith Cowan University, Melbourne's Florey Institute and the National Ageing Research Institute.

The CSIRO said the research, titled 'Association of Basal Forebrain Atrophy With Cognitive Decline in Early Alzheimer Disease' was published in the journal Neurology and available at: https://www.neurology.org/doi/10.1212/WNL.0000000000209626.

The Organisation said the research included neuro-imaging, biomarker and neuro-psychological assessments at 18-month intervals.

The study lead author and CSIRO researcher Dr Ying Xia said early diagnosis was critical for the management of Alzheimer's disease symptoms".

"Our results show how the atrophying of the basal forebrain, a key brain region for learning and memory and part of the cholinergic system, could indicate the presence of the disease well before symptoms occur," Dr Xia said.

Dr Xia said recently developed drugs that cleared amyloid plaques held promise, but it was not yet known "whether targeting these plaques address the underlying causes of memory and attention decline … [and were] only effective in up-to 30 percent of cases".

The CSIRO said the findings might assist in the development of drugs to reduce the decline in brain function, including working with drugs currently undergoing regulatory approval, which clear amyloid plaques from the brain, to amplify their cognitive effects.

The Organisation said the next stage of research involved "identifying how early the impairment of the cholinergic system occurs and when to administer cholinergic drug treatments to stabilize cognitive decline".

ALTERITY THERAPEUTICS

Alterity says three of seven evaluable patients in its phase II trial of ATH434 for multiple system atrophy (MSA) show an improvement in daily living functions.

Last year, Alterity it had begun a 15-patient, open-label, phase II trial of ATH434, called 'ATH434-202', in patients with multiple system atrophy, in addition to its 60-patient phase II trial, (ATH434-201) but included patients with more advanced multiple system atrophy, compared to patients in earlier stages of the disease in the first study (BD: May 30, 2023).

Today, Alterity said 10 patients had received 75mg ATH434 orally twice daily, and the interim analysis was from seven patients treated for six months or more.

The company said that following six months of treatment three of seven patients, (42.85%), showed an improvement on the unified MSA Rating Scale (UMSARS), which showed "reduced disability on activities of daily living" and two of seven patients (28.6%), were clinical responders with stable or improved neurological symptoms.

The company said the two clinical responders "on average had reduced accumulation of iron on [magnetic resonance imaging] in the substantia nigra, putamen and globus pallidus and stable levels of [neurofilament light chain], a marker of axonal injury, when compared to participants who declined".

Alterity said although the data was preliminary it saw "a positive trend with the current participant patient outcomes" with ATH434 generally well-tolerated and most adverse events mild to moderate with no serious drug-related adverse events reported.

Alterity was up 0.2 cents or 40 percent to 0.7 cents with 191.1 million shares traded.

PYC THERAPEUTICS

PYC says it has dosed the first cohort with 30 micrograms (µg) of VP-001 in its six-patient multiple-ascending dose study for retinitis pigmentosa type 11 (RP11).

Last week, PYC said it had begun the multiple-ascending dose study to assess the VP-001's safety, tolerability and efficacy at 30µg and 75µg following positive safety results from its single-ascending dose study (BD: Jul 1, 10, 2024).

Today, the company said the three patients in cohort one received an initial 30 microgram dose of VP-001 in one eye through intra-vitreal administration and were scheduled to receive two more doses in the same eye at intervals of eight weeks.

PYC said it expected to receive both safety and efficacy data from the trial "before the end of this year", with the data to be used for a registrational trial in 2025.

PYC was unchanged at 12 cents with 2.3 million shares traded.

IMMUTEP

Immutep says it has approval for a first in-human, 49-volunteer, phase I trial of its IMP761 for auto-immune diseases in the Netherlands.

Earlier this year, Immutep said the Leiden, Netherlands' Centre for Human Drug Research would conduct a phase I trial of its IMP761 for auto-immune disease (BD: Apr 18, 2024).

Today, the company said IMP761 was the first therapeutic LAG-3 agonist antibody and had been identified as a promising target for agonist immunotherapy to treat rheumatoid arthritis, type 1 diabetes, multiple sclerosis and other auto-immune diseases.

Immutep said the study would assess safety, pharmaco-kinetics and pharmaco-dynamics, with the first participants expected to be enrolled by October 2024, and data this year.

Immutep chief scientific officer Prof Frédéric Triebel said trial clearance was "a significant milestone".

"Blocking LAG-3 with an antagonist antibody in cancer patients unleashes the power of the anti-tumor T-cell responses, but also leads to auto-immunity in a fraction of the patients," Prof Triebel said. "This has put LAG-3 at the centre of auto-immune disorders as a co-inhibitory receptor that downplays the T-cell receptor response."

"Using IMP761, an agonist LAG-3 antibody, to reinforce this physiological upstream control of the T-cell response represents a new approach to silence the few aggressive T cells that lead to auto-immune diseases," Prof Triebel said.

Immutep fell half a cent or 1.7 percent to 29.5 cents with 5.9 million shares traded.

NEXT SCIENCE

Next Science says it has a $US5,000,000 ($A7,420,000) loan at 12.0 percent a year from Melbourne's Tiga Trading Pty Ltd for "general working capital requirements".

Next Science said with the loan it had signed an option deed to issue Tiga Trading, a company associated with Alex Waislitz's Thorney Investment Group, 5,000,000 options exercisable at 42 cents within three years.

The company said the unsecured loan was payable by July 17, 2026.

Next Science managing-director Harry Hall said the company reviewed "its funding requirements on an ongoing basis and believes it has sufficient working capital to meet its obligations".

"However … the company has explored funding options to provide a buffer against unexpected financial challenges and the flexibility to respond should investment opportunities arise," Mr Hall said.

Next Science was up two cents or eight percent to 27 cents.

IMAGION BIOSYSTEMS

Imagion says it has a deed of variation on its draw-down equity facility with Mercer Street Global Opportunity Fund to lower the floor price 92 percent from 50 cents to four cents.
Last year, Imagion said it had taken an up-to $15 million draw-down facility with New York's Mercer Street, with an initial draw-down of $1.5 million according to the terms of the agreement, with a floor price of 1.25 cents a share.
Last year, Imagion approved a 40-to-one consolidation, with more than 30 percent against the consolidation and the issue of 19,500,000 options to directors (BD: Nov 13, 2023).
Today, the company said the amendments stated that if it raised between $10 million and $15 million in a capital raising "Mercer may require repayment by the company of some or all of up-to 50 percent" of the drawn down amount, with capital raisings of more than $15 million allowing Mercer to seek repayment of up-to 100 percent.
Imagion said the maturity date of the first and second draw-downs of convertible notes had been extended from 18 months to 30 months from their issue date, with the remaining draw-downs to be repaid within an unchanged 18 months.
Earlier this year, the ASX said it had suspended Imagion under Listing Rule 17.5 for "not lodging the relevant period report by the due date" (BD: Apr 2, 2024).
Today, the company said its suspension had constituted an "event of default" under its Mercer agreement, but that Mercer had waived all rights of redemption that would otherwise have been triggered by the suspension.
Imagion said in consideration, it would issue 3,000,000 shares to Mercer, with 650,000 shares subject to shareholder approval.
Imagion fell half a cent or 7.35 percent to 6.3 cents.

IMRICOR MEDICAL SYSTEMS

Imricor has requested a trading halt pending an announcement "in relation to a proposed capital raising".
Trading will resume on July 19, 2024, or on an earlier announcement.
Imricor last traded at 59 cents.

BOTANIX PHARMACEUTICALS

Sydney's Insignia Financial Ltd says it has increased its substantial shareholding in Botanix from 112,295,811 shares (8.60%) to 187,150,760 shares (10.34%).
Insignia said it bought and sold shares between July 24, 2023 and June 28, 2024, with the single largest purchase 27,686,601 shares for $8,305,980, or 30 cents a share.
Botanix was up one cent or 2.6 percent to 39.5 cents with 18.5 million shares traded.

ALLEGRA MEDICAL TECHNOLOGIES

Allegra director Dr Nicholas Hartnell says he has increased his substantial holding in the company from 69,834,014 shares (58.38%) to 71,967,146 shares (60.17%).
In May, Allegra said Dr Hartnell would pay 0.4 cents a share in a cash bid, valuing it at $478,444; and later, filed his bidder's statement (BD: May 27, Jun 20, 2024).
Allegra was in a suspension and last traded at 2.9 cents.