Biotech Daily

Tuesday May 30, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: MICRO-X UP 33%; ONCOSIL DOWN 8%**

*** FDA APPROVES INCISIVE BLUECHECK FOR TOOTH DECAY**

*** SYDNEY UNI, PHAROS AI DRUG DEVELOPMENT**

*** ALCIDION $3.3m NHS TRUST CONTRACT RENEWALS**

*** OPTISCAN RIGHTS TO RAISE $16.7m**

*** ALTERITY STARTS 2nd PHASE II ATH434 STUDY IN MSA**

*** IMMURON BEGINS US ARMY TRAVELAN DIARRHOEA TRIAL**

*** NEUROTECH MARIJUANA NTI164 PSYCH TRIAL EXTENDED**

*** FIREBRICK, TGA NASODINE APPEAL DEFERRED**

*** MICRO-X PLEADS 'ARGUS NEWS' TO ASX 39% QUERY**

*** INCANNEX APPOINTS PSYCHEDELIC ADVISERS**

MARKET REPORT

The Australian stock market fell 0.11 percent on Tuesday May 30, 2023, with the ASX200 down 8.1 points to 7,209.3 points. Thirteen of the Biotech Daily Top 40 stocks were up, 17 fell and 10 traded unchanged.

Micro-X was the best, as yesterday's news filtered through to investors (see below), up three cents or 33.3 percent to 12 cents, with 3.1 million shares traded. Medical Developments improved 10.3 percent; Universal Biosensors climbed 6.25 percent; Nova Eye was up 5.9 percent; Cyclopharm and Orthocell rose more than four percent; Polynovo and Proteomics were up three percent or more; Neuren and Telix were up more than one percent; with Avita, CSL, Emvision, Pro Medicus and Resmed up by less than one percent.

Oncosil led the falls, down 0.1 cents or 7.7 percent to 1.2 cents, with 1.1 million shares traded. Actinogen and Dimerix lost more than six percent; Imugene and Paradigm fell more than four percent; Atomo, Compumedics, Cynata, Genetic Signatures and Mesoblast were down more than three percent; Amplia, Kazia and Next Science shed more than two percent; Alcidion and Immutep were down one percent or more; with Clinuvel, Cochlear and Nanosonics down by less than one percent.

INCISIVE TECHNOLOGIES

Incisive Technologies says the US Food and Drug Administration 510(k) has cleared its Bluecheck early caries, or tooth decay, detection and monitoring device.

The Melbourne-based Incisive said Bluecheck aided the detection of early caries in dental examinations by binding to active caries lesions and showing them with a visible blue color, providing dental professionals a direct and objective measure of the disease.

The company said early caries was a precursor to cavities and recognized by the World Health Organisation as “the world’s most prevalent chronic disease”.

Incisive chief scientific officer Dr Johnathon Mangum said the Bluecheck device was a molecule that used the natural hydroxy-apatite-binding chemistry of proteins to target porous surfaces and sub-surface lesions.

“It is a specifically designed bio-molecule, consisting of protein, linker and dye, that selectively and reversibly binds to sites of dental demineralization,” Dr Mangum said.

“Bluecheck is painted on, then a simple rinse washes away unbound Bluecheck, to reveal the active caries via the remaining bound blue color,” Dr Mangum said.

Incisive chief executive officer Dr Kerry Hegarty said the company saw experts were driving a shift to a prevention focus “whereby earlier detection of caries enables prevention medicaments to be used, effectively halting the demineralization process”.

“However, finding dental caries early is challenging,” Dr Hegarty said.

“The use of Bluecheck lets clinicians quickly and accurately supplement their evaluation, thereby aiding the identification of early caries,” Dr Hegarty said.

“Earlier diagnosis of dental caries is key to patient education, use of remineralisation therapies and ongoing monitoring for caries progression,” Ms Hegarty said.

Ms Hegarty said Incisive had worked with dentists, orthodontists and researchers to understand how Bluecheck could support a shift to improve patient outcomes.

Incisive said Bluecheck was its first commercialized product and it had a number of research and collaboration projects to understand Bluecheck’s role in clinical management and develop the technology for other innovations.

The company said its device would be launched initially in the US from September, with other markets to follow.

Incisive Technologies is a private company.

UNIVERSITY OF SYDNEY

The University of Sydney says it will collaborate with Pharos Therapeutics to use artificial intelligence to identify compounds for cancer and rare disease treatments.

The University said that the agreement with the Australian subsidiary of South Korean pharmaceutical company Pharos Ibio would provide access to Pharos’ artificial intelligence drug development platform Chemiverse.

The University of Sydney said Pharos would benefit from working with its researchers and drug-discovery infrastructure.

The University’s Drug Discovery Initiative director Prof Michael Kassiou said the process of developing drugs for treating disease was highly complex and the Chemiverse platform would “greatly enhance our ability to develop novel treatments for unmet medical need”.

The University said Chemiverse could be used through the drug development process from target discovery to lead compound generation “by incorporating about 230 million pieces of big data and advanced algorithms”.

University of Sydney pro-vice chancellor of research enterprise Prof Julie Cairney said the University was “committed to translating our fundamental research into real-world solutions”.

ALCIDION GROUP

Alcidion says it has renewed contracts with two UK National Health Service hospitals for its Silverlink patient care system for a combined value of $3.3 million.
Alcidion said the Royal Wolverhampton NHS Trust contract had been extended for two years and the University Hospitals Dorset NHS Foundation Trust for three years.
The company said that both organizations were long-standing users of the patient care systems.
Alcidion managing-director Kate Quirke said the company had renewed contracts with all four patient care system customers - Moorfields Eye Hospital, Liverpool Heart and Chest Hospital, Royal Wolverhampton NHS Trust and University Hospitals Dorset NHS Foundation Trust – “that were identified as key success indicators following the acquisition of Silverlink PCS Software” in 2021.
“The acquisition of Silverlink’s patient administration system and its alignment with our existing Miya Precision platform has enabled us to increase revenues and expand our footprint across the UK by providing direct access to an additional 11 Trusts,” Ms Quirke said.
In 2021, the company said it had completed the acquisition of Newcastle, England-based Silverlink Software for its patient administration system, with a $55 million capital raise to pay for the GBP30.0 million ($A56.3 million) purchase price for Silverlink, with a further GBP3.0 million ($A5.6 million) subject to the earn-out, based on the successful renewal of selected customers by March 31, 2024 (BD: Dec 7, 8, 16, 2021).
Today, Alcidion said the signing of the two contracts triggered a payment of GBP1.5 million ($A2.8 million) which was 50 percent of the earnout figure agreed in the Silverlink acquisition.
Alcidion fell 0.1 cents or one percent to 9.9 cents with 2.6 million shares traded.

OPTISCAN IMAGING

Optiscan says it hopes to raise up-to $16,698,816 in a one-for-three, pro rata entitlement offer at eight cents a share.
Optiscan said existing substantial shareholder Peters Investments Pty Ltd and Orchid Capital Investments Pte Ltd would underwrite $6,950,000 and $2,863,733 of the offer, respectively.
The company said the offer was open to all Australian, New Zealand and Singapore shareholders and that it included a shortfall facility.
Optiscan said that the funds raised in the rights issue would be used for its research and development projects including rigid and flexible surgical applications of its confocal microscope system, as well as image capture, artificial intelligence and tele-pathology capabilities and to undertake clinical studies and for working capital.
The company said the record date would be June 2, the offer would open on June 7 and close on June 23, 2023.
Optiscan chief executive officer Dr Camile Farah said the company was moving from a research and development enterprise and original equipment manufacturer supplier to a “pure-play medical device manufacturer and digital solution provider”.
“As the company looks forward to its first standalone [US Food and Drug Administration]-cleared medical device, the time is right to unleash the power of our platform digital imaging technology and develop a portfolio of products and services,” Dr Farah said.
Optiscan fell 1.1 cents or 11 percent to 8.9 cents.

ALTERITY THERAPEUTICS

Alterity says it has begun a 15-patient, open-label, phase II trial of ATH434 for patients with multiple system atrophy, a second study of ATH434 in the disease.
In 2021, Alterity said it had New Zealand approval for the 60-patient, randomized, double-blind, controlled, phase II trial of ATH434 for multiple system atrophy (BD: Dec 14, 2021).
Today, the company said the 15-patient study was in addition to the 60-patient trial but included patients with more advanced multiple system atrophy, compared to patients in earlier stages of the disease in the first study.
Alterity said the trial would assess the efficacy of ATH434 on bio-markers that measured target engagement and were relevant to the underlying pathology of the disease.
The company said the bio-markers included brain iron and aggregating alpha-synuclein, which were important contributors to multiple system atrophy pathology and appropriate targets to demonstrate drug activity.
Alterity said the patients would receive treatment for 12-months and the impact of the drug on brain iron would be evaluated using magnetic resonance imaging.
Alterity chief executive officer Dr David Stamler said the biomarker study complemented the ongoing phase II trial and allowed it to “evaluate the effect of ATH434 on two multiple system atrophy populations of differing severity”.
Alterity was up 0.15 cents or 23.1 percent to 0.8 cents with 9.9 million shares traded.

IMMURON

Immuron says the US Army has approved a 60-patient trial of Travelan in health adults for infectious diarrhoea from entero-toxigenic Escherichia coli.
Last year, Immuron said the US Food and Drug Administration approved its Travelan investigational new drug application (BD: Jan 22, 2023).
Today, the company said the US Army Medical Research and Development Command Office of Human and Animal Research Oversight had approved the trial.
Immuron said the trial would evaluate the safety and protective efficacy of Travelan compared to a placebo in a controlled human infection model, with the primary efficacy outcome the prevention and or a reduction of moderate to severe diarrhoea.
The company said the trial would be conducted by the Waltham, Massachusetts-based Pharmaron CPC at its research facility inpatient unit in Baltimore, Maryland.
Immuron said the first cohort of 30 patients was expected to be enrolled by the end of July, the second cohort during October 2023 and headline results by July 2024.
Immuron was up half a cent or 6.3 percent to 8.4 cents.

NEUROTECH INTERNATIONAL

Neurotech says it has ethics committee approval to extend its phase I/II trial of the marijuana -based NTI164 for children with neuro-psychiatric disorders.
In February, Neurotech said it treated the first patient in the trial at Sydney’s Children’s Hospital at Westmead and Melbourne’s Monash Medical Centre (BD: Feb, 16, 2023).
Earlier this month, the company said it had recruited 15 children with paediatric auto-immune neuro-psychiatric disorders associated with streptococcal infections (Pandas) and paediatric acute-onset neuro-psychiatric syndrome (Pans) (BD: May 3, 2023).
Today, the company said the ethics committee extension would allow children to continue to receive the NTI164 treatment after they turned 18 years of age.
Neurotech fell 0.2 cents or 4.3 percent to 4.5 cents.

FIREBRICK PHARMA

Firebrick says its conciliation meeting to appeal the Australian Therapeutics Goods Administration's decision not to approve Nasodine has been deferred.
Last year, Firebrick said it would appeal against the TGA decision not to approve its Betadine-based anti-viral Nasodine nasal spray based on the data (BD: Mar 1, 2022).
In December, the company said it, the TGA and the Administrative Appeals Tribunal (AAT) had agreed to a Nasodine appeal decision timetable with a conciliation conference set for on or about May 30, 2023 (BD: Dec 2, 2022).
Today, Firebrick said the AAT requested a deferral "due to the unavailability of the nominated AAT member" on the set date and that a rescheduled date was yet to be agreed by the parties.
Firebrick said it had submitted its statement of issues facts and contentions on March 2, 2023 and had received the TGA's statement on May 25, which was originally scheduled for May 12, which "would have allowed the company only four days to file a response and fully prepare for the conciliation".
The company said it supported the deferral of the conciliation and would update the market on a revised date when it was agreed.
Firebrick was up 1.5 cents or 9.4 percent to 17.5 cents.

MICRO-X

Micro-X has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price rose 38.9 percent from 9.0 cents on May 29 to 12.5 cents today, May 30, 2023 and noted a "significant increase" in the trading volume.
Micro-X said that yesterday it announced "successful field testing" of its Argus improvised explosive device detector system (BD: May 29, 2023).
Micro-X closed up three cents or 33.3 percent to 12 cents with 3.1 million shares traded.

INCANNEX HEALTHCARE

Incannex says it has appointed Dr Bill Richards, Dr Andrea Jungaberle and Prof Matthew Johnson to the advisory board of its Clarion Clinics Group subsidiary.
Earlier this year, Incannex said it had plans to open psychedelic-assisted psychotherapy clinics, with the first expected to open this year (BD: Mar 16, 2023).
Today, the company said Clarion was a collaborative venture with three Australian psychedelic drug professionals, with the first patients expected by October 2023.
Incannex said Dr Richards was the director of therapy at the Rockville, Maryland-based Sunstone Therapies, Dr Jungaberle was chief medical officer of Berlin's Ovid Clinics and Prof Johnson was a scientist at the Baltimore, Maryland-based Johns Hopkins Centre for Psychedelic and Consciousness Research.
Incannex director Peter Widdows said the appointments to the advisory board would help ensure "world-leading effective treatments" were provided in "an ethical and safe way".
Incannex was unchanged at 11.5 cents with 1.2 million shares traded.