Biotech Daily

Tuesday March 14, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ACTINOGEN UP 11%; PRESCIENT DOWN 9%**

*** FEDERAL $15m FOR MONASH UNIVERSITY MITOCHONDRIAL STUDY**

*** FEDERAL $382m FOR 193 MEDICAL PROJECTS**

*** ASX CENSURES CRESO; CRESO RESPONDS**

*** OPTISCAN: ORAL CANCER MICROSCOPE 'EXTREMELY ACCURATE'**

*** PATRYS PAT-DX3 'REDUCES TUMOR GROWTH BY 71%, IN MICE'**

*** ANTISENSE STARTS ATL1102 MONKEY TOXICOLOGY STUDY**

*** PARADIGM PPS PHASE III TRIAL APPROVED IN EUROPE**

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*** IMMUTEP; US, SPAIN APPROVE IMP321 BREAST CANCER TRIAL**

*** ALTERITY US COMPOUNDS PATENT, PBT2 TO PROF COLIN MASTERS**

*** NEUROSCIENTIFIC 'EMTINB DELAYS MULTIPLE SCLEROSIS, IN MICE'**

*** BIONOMICS TELLS ASX: 'DON'T KNOW IF INFORMATION MATERIAL'**

*** INCANNEX TAKES 'PSYCHEDELIC PROGRAM' HALT TO SUSPENSION**

*** HARBOUR TAKES 15% OF VOLPARA**

*** PRO MEDICUS CHAIR PETER KEMPEN SELLS 50k SHARES**

*** EMVISION APPOINTS ALAN COULTHARD TO CLINICAL ADVISORY BOARD**

*** BIO-MELBOURNE, VICTORIA MEDTECH MANUFACTURING SEMINARS**

MARKET REPORT

The Australian stock market fell 1.41 percent on Tuesday March 14, 2023, with the ASX200 down 99.9 points to 7,008.9 points. Ten of the Biotech Daily Top 40 stocks were up, 19 fell, nine traded unchanged and two were untraded. All three Big Caps fell.

Actinogen was the best, up 0.7 cents or 10.6 percent to 7.3 cents, with 2.4 million shares traded. Neuren climbed a further 9.7 percent; Pharmaxis rose 2.1 percent; Clinuvel, Immutep, Medical Developments and Starpharma were up more than one percent; with Avita, Paradigm and Volpara up by less than one percent.

Prescient led the falls, down one cent or 8.7 percent to 10.5 cents, with 1.1 million shares traded. Cynata lost 6.7 percent; Antisense and Oncosil were down more than five percent; Micro-X and Orthocell fell four percent or more; Alcidion, Imugene and Kazia were down more than three percent; Mesoblast, Nanosonics, Nova Eye, Opthea and Telix shed more than two percent; Cochlear, CSL, Impedimed, Proteomics and Resmed were down one percent or more; with Genetic Signatures, Next Science and Pro Medicus down by less than one percent.

FEDERAL GOVERNMENT

The Federal Government says the Medical Research Future Fund will grant $15 million to Monash University for research to prevent inherited mitochondrial disease.
A media release from the Federal Minister for Health and Aged Care Mark Butler said the money would go to Monash University's Mitohope mitochondrial donation pilot program.
The Government said a Monash University trial would determine the safety, efficacy and feasibility of using mitochondrial donation reproductive technology in clinical practice.
The media release said the project aimed to assist women to have children who do not inherit the predisposition to mitochondrial disease and would help determine the best way to safely offer mitochondrial donation to Australian women with the disease.
"Mitochondrial disease is a really challenging condition to navigate," Mr Butler said. "It can be debilitating with physical and neurological symptoms that are often not fully understood, and there is no cure."

FEDERAL GOVERNMENT

The Federal Government says the Medical Research Future Fund will provide $382 million for 193 medical research projects, including $32 million for First Nations' people.
A media release from the Federal Minister for Health and Aged Care Mark Butler said the University of Newcastle would be awarded $2 million to support Aboriginal mothers in New South Wales to stop smoking during pregnancy and after, and that the Sax Institute would be awarded $1.5 million to evaluate prevention programs to support healthy aging among Aboriginal people.
The media release said 19 grants worth more than $32.3 million were related to First Nations health, with 13 grants worth more than $16.9 million related to mental health.
A complete list of all grants is at: https://bit.ly/3YFXAYB.

AUSTRALIAN STOCK EXCHANGE, CRESO PHARMA

ASX says it has formerly censured Creso Pharma for breaching ASX listing rule 10.11, prohibiting companies from issuing shares to related parties without shareholder approval.
In October, Creso said it had breached Listing Rule 10.11 by not stating that Alvin Blumenthal's Suburban Holdings Pty Ltd was a related party to a February $5 million placement (BD: Feb 25, Oct 25, 2022).
In December 2022, the company said the breach was not uncovered earlier because Everblu, which was controlled by Alvin Blumenthal's son Adam Blumenthal, had "managed many placements for the company prior to this, without concern or error, and therefore there was no reason for the company to question the participants in this placement" (BD: Dec 6, 2022).
Today, the ASX told Biotech Daily that Suburban had "agreed to dispose of all [14,492,755] shares it received in the placement within six weeks" and that it had directed Creso not to issue the free attaching options entitled to Suburban from the placement, and that "any profit made on the disposal of the holding will be donated to an entity that is listed with the Australian Charities and Non-For-Profits Commission as a charity".
The ASX told Biotech Daily that Creso would not incur any pecuniary penalty as "the censure itself is the enforcement action".
In a separate announcement, Creso said that it did "not consider a formal censure appropriate … [as it had provided] seven examples of other listed companies breaching Listing Rule 10.11 in the last three years which did not result in a censure".
Creso fell 0.05 cents or 4.55 percent to 1.05 cents with 11.2 million shares traded.

OPTISCAN IMAGING

Optiscan says interim results show its oral imaging endo-microscope to be “extremely accurate” for the diagnosis of oral cancer and pre-cancer.

Optiscan said the study was conducted by Prof Camile Farah prior to his appointment as managing-director of the company and assessed 47 patients presenting with 63 distinct oral mucosal lesions using its real-time, in-vivo, confocal laser endo-microscope.

The company said its microscope was “extremely accurate” for the diagnosis of oral cancer (squamous cell carcinoma) and precancer (epithelial dysplasia) in assessing its recently acquired intellectual property.

Last year, Optiscan said that it would issue 6,000,000 shares to managing-director Prof Camile Farah for his clinical and histopathological datasets, subject to shareholder approval (BD: Oct 25, 2022).

Today, the company said 100 percent of cancer cases were diagnosed correctly using its confocal laser endo-microscope, with diagnostic accuracy at 88.9 percent for dysplasia and carcinoma, 86.8 percent sensitivity and 92 percent specificity.

Optiscan said that positive predictive value was 94.3 percent and negative predictive value was 82.1 percent.

Prof Farah said the confocal laser endo-microscope “permits the discrimination between dysplastic and non-dysplastic pathology and demonstrates near-perfect agreement with traditional consensus histopathology without the need for physical tissue biopsy”.

Optiscan chair Robert Cooke said the results from the interim study show that “Optiscan’s fluorescence-based [confocal laser endo-microscope] device is a highly accurate, easy-to-use, rapid and slide-free point-of-care optical imaging technology for diagnosing oral cancer and pre-cancer”.

The company said the results of this interim analysis and data contained within its oral imaging datasets would support its US Food and Drug Administration de-novo classification application for the Invivage product for oral tissue imaging.

Optiscan was up 0.2 cents or 2.2 percent to 9.4 cents.

PATRYS

Patrys says a colon cancer study in mice has shown that its full-size immunoglobulin G (IgG) deoxymab drug PAT-DX3 reduces the growth of certain tumors by 71 percent.

Patrys said that PAT-DX3 had the ability to enter cancer cells and the cell nucleus and block the DNA damage response (DDR) systems.

The company said tumors with a compromised DDR system had a 71 percent reduction in growth, while tumors with an intact DDR mechanism had a reduced growth of 35 percent.

Patrys chief executive officer Dr James Campbell said the study confirmed “the potential to use deoxymabs as a single agent to treat cancers which have pre-existing mutations that compromise their DDR systems, including BRCA2 negative breast cancer and other cancers”.

“In addition, Patrys is looking at using deoxymabs in combination with DNA damaging therapies, such as radiation and chemotherapies, and as a delivery agent for small molecules and nucleic acids,” Dr Campbell said.

The company said the study evaluated the accumulation of DNA breaks in tumor cells, with all tumors in mice treated with PAT-DX3 showing an accumulation of DNA damage and with the level of DNA damage significantly higher in DDR deficient tumors.

“This study was requested by a potential partner as part of Patrys’ ongoing business development activities,” Dr Campbell said.

Patrys was unchanged at 2.4 cents with 6.6 million shares traded.

ANTISENSE THERAPEUTICS

Antisense says it has begun its nine-month monkey toxicology study of ATL1102, to support the US investigation of ATL1102 for Duchenne muscular dystrophy.
In 2021, Antisense said the US Food and Drug Administration required updated clinical and toxicology protocols to be resubmitted to lift the ATL1102 partial clinical hold and later said it planned a nine-month chronic monkey toxicology study to support the dosing of patients with ATL1102 beyond six months (BD: Aug 12, Dec 9, 2021).
Last year, the company said it expected the nine-month toxicology study of ATL1102 would allow the FDA to lift the partial clinical hold on ATL1102 limiting dosing to 25mg weekly for six months (BD: Nov 22, 2022).
Today, Antisense said the results from the study would be due about the same time as the results from the blinded phase of the ATL1102 phase IIb Duchenne muscular dystrophy, which could allow it to share data with the FDA and other regulatory bodies for discussions on registration of the drug.
Antisense fell 0.5 cents or 5.3 percent to nine cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has European approval for its 470-patient phase III trial of injectable pentosane polysulphate sodium (PPS) for knee osteo-arthritis pain.
Last year, Paradigm said it has dosed the first two of 930 patients in its randomized, double- blind, placebo-controlled, phase III trial of PPS, or Zilosul, for knee osteo-arthritis (BD: Jan 16, 2022).
Today, Paradigm said it had approval from the European Clinical Trial Information System to begin its trial at up-to seven sites in Belgium, Poland and the Czech Republic.
Paradigm managing director Paul Rennie said the study continued “to gain acceptance and approval by key regulatory bodies”.
Paradigm was up one cent or 0.7 percent to $1.37.

TRUSCREEN

Truscreen says a 507-patient clinical evaluation of Truscreen Ultra for cervical cancer showed sensitivity and specificity better than or close to liquid-based cytology.
Truscreen said results from the evaluation completed with the Riyadh, Saudi Arabia-based Dr Sulaiman Al-Habib Medical Group showed Truscreen Ultra sensitivity was at 83.3 percent and specificity at 95 percent, while liquid-based cytology (LBC) was 66 percent and 98 percent, respectively.
The company said the lead investigator Dr Majed Alhudhud said there was “no national program for cervical cancer screening in Saudi Arabia, and we see Truscreen as a strong alternative to the standard LBC”.
“In the study we found Truscreen to be as effective as LBC, while also providing real time results and resolving many of the issues faced with potential patient follow-up when using LBC,” Dr Alhudhud said.
Truscreen chief executive officer Dr Beata Edling said the company was delighted with the results of its clinical evaluation in Saudi Arabia and the Middle East, which validated evaluations conducted in China, Australia and Vietnam.
“We looked forward to enhanced women’s health care in Saudi Arabia and to the neighboring [Arabian] Gulf countries,” Dr Edling said.
Truscreen was unchanged at three cents.

IMMUTEP

Immutep says it has US and Spain approval for a 70-patient, phase II/III trial of eftilagimod alpha (efti, or IMP321) for metastatic HER2-neg/low breast cancer.

In January, Immutep said the US Food and Drug Administration agreed to an up-to 70-patient, phase II/III trial of eftilagimod alpha with chemotherapy for metastatic breast cancer, which, subject to approvals would begin by April 2023 (BD: Jan 22, 2023).

Today, the company said it had approval for its trial of 30mg or 90mg of eftilagimod alpha combined with paclitaxel for treating breast cancer with enrolment to begin in April, 2023.

Immutep said an open-label lead-in component of 12 patients would test the 90mg efti dose in combination with paclitaxel, to be followed by a randomized portion of the phase II trial of up-to 58 patients receiving 30mg efti or 90mg efti to determine the optimal biological dose in combination with paclitaxel.

The company said it had included triple-negative breast cancer patients, which with HR+/HER2-neg/low metastatic breast cancer made up 78 percent of all cases.

Immutep chief executive officer Marc Voigt said with its novel mechanism of action to activate antigen-presenting cells efti had "to date safely improved clinical outcomes from anti-[programmed death ligand 1] therapies and standard-of-care chemotherapy".

"The selected phase II/III trial design allows us to move forward with a risk-balanced approach in [metastatic breast cancer] as we continue our prioritized late-stage clinical development with anti-[programmed death ligand 1] therapy in first line head and neck squamous cell carcinoma and firs line non-small cell lung cancer," Mr Voigt said.

Immutep was up half a cent or 1.9 percent to 27 cents with 1.7 million shares traded.

ALTERITY THERAPEUTICS

Alterity says it has been granted a US patent for acyl hydrazone compounds and licenced them and PBT2 to the Florey Institute of Neuroscience's Prof Colin Masters.

Alterity said that Prof Colin Masters would "advance these compounds for the treatment of Alzheimer's and related diseases" and it had granted the rights to the acyl hydrazone patent and exclusive licence to develop and commercialize both acyl hydrazone and PBT2 in exchange for future royalties of net sales.

Alterity said Prof Masters was a "pre-eminent researcher" of the amyloid beta protein that forms the cerebral plaques in Alzheimer's disease, and had "laid the foundation for recently approved treatments" of the disease.

Alterity chief executive officer Dr David Stamler said the new patent was "a testament to the ongoing success of our discovery team as they continue to generate novel small molecules with potential to treat important neurodegenerative diseases".

"We are excited to extend our long-standing collaboration with Prof Masters, whose understanding of the role of beta amyloid in Alzheimer's disease pathogenesis and research cannot be overstated," Dr Stamler said.

"Because the [acyl hydrazone] compounds act similarly to PBT2, this deal makes good sense for future research and development to occur alongside one another," Dr Stamler said. "This arrangement broadens the opportunity for both programs since our clinical development efforts are currently focused on Parkinsonian disorders such as multiple system atrophy and Parkinson's disease."

Prof Masters said he looked "forward to continued collaborations with Alterity as we look to add value to existing patents and find ways to develop novel Alzheimer's disease-modifying therapeutics using the latest technologies employing imaging and biofluid biomarkers".

Alterity was unchanged at 0.9 cents with 7.3 million shares traded.

NEUROSCIENTIFIC BIOPHARMECEUTICALS

Neuroscientific says its 21-day study of three doses of Emtinb versus placebo for multiple sclerosis in mice showed “a statistically significant positive treatment effect”.
Neuroscientific said the mice were dosed with 10mg/kg, 20mg/kg or 40mg/kg of Emtinb and compared to a clear decline in body weight in the placebo group, the 10mg/kg and 20mg/kg groups had a prolonged maintenance of body weight during the treatment period.
The company said the study supported the use of Emtinb as a neuro-protective agent and a treatment for neuro-degenerative diseases, particularly multiple sclerosis.
Neuroscientific executive chair Paul Rennie said “Emtinb had a statistically significant positive clinical effect in this industry standard pre-clinical model of [multiple sclerosis]”.
“This pre-clinical data will be used to complete the efficacy section for [the company’s] planned submission for its first-in-human, phase I clinical trial,” Mr Rennie said.
Mr Rennie said Neuroscientific had made progress in the safety and purity sections of its ethics committee submission and said the company was focused on preparing its submission to the Australian Therapeutic Goods Administration by October 2023.
Neuroscientific fell one cent or 10.3 percent to 8.7 cents.

BIONOMICS

Bionomics has told the ASX “it is not clear whether a reasonable person would expect the information … would or would not have a material effect on the price or value of its securities”.
Answering an ASX ‘Aware’ question Bionomics said “no definite decisions have been taken … about the possible further development of the BNC210 compound in relation to [social anxiety disorder] in particular any further clinical trials, apart from an intention to apply for and conduct an end-of-phase II meeting with the [US Food and Drug Administration] as stated in the announcement and certain preliminary activities”.
Last week, the company released a further detailed analysis of its Bionomics 151-patient phase II trial of BNC210 for social anxiety disorder confirming last year’s announcement that the trial “did not meet the primary endpoint [but] consistent trends were observed” (BD: Dec 19, 2022; Mar 9, 2023).
In a separate announcement last week, Bionomics said that it was aware of information concerning it that had not been announced, which if known, could explain the recent trading in its securities.
In a price query, the ASX noted a 15.6 percent rise in the price of Bionomics’ shares from a low of 3.2 cents to a high of 3.7 cents on March 8, 2023, and a “significant increase in the volume of … securities traded”.
The ASX asked Bionomics if it was aware of any information that had not been announced, that could explain the recent trading in its securities?
Bionomics said: “Yes, at the time of receipt of the letter from ASX, Bionomics was aware of information concerning it that has not been announced, which, if known by some in the market, could explain the recent trading in its securities” (see above).
According to Commsec data, Bionomics was up 0.9 cents or 33.3 percent to 3.6 cents on March 8 and a further 0.7 cents or 19.4 percent to 4.3 cents on March 9, 2023.
Today, the company said it became aware of the results of its study of BNC210 for acute treatment of social anxiety on March 8, 2023.
The company said that approval from the board was not obtained until very shortly before the release of its announcement of the results on March 9, 2023 and noted that Bionomics shares were in a trading halt from March 8, 2023 until the announcement.
Bionomics fell 0.1 cents or 3.2 percent to three cents with 4.9 million shares traded.

INCANNEX HEALTHCARE

Incannex says it has requested a voluntary suspension to follow last week's trading halt for an update on its psychedelic program (BD: Mar 10, 2023).
Incannex requested the suspension until March 15, 2023 or an announcement.
Incannex last traded at 14.5 cents.

VOLPARA HEALTH TECHNOLOGIES

Harbour Asset Management says it has increased its substantial holding in Volpara from 35,593,522 shares (14.118%) to 38,417,837 shares (15.120%).
The Wellington, New Zealand-based Harbour said that between January 25 and March 13, 2023 it bought 2,824,315 shares for $2,207,884, or an average of 78.2 cents a share.
Volpara was up half a cent or 0.7 percent to 73.5 cents.

PRO MEDICUS

Pro Medicus says chair Peter Kempen has sold 50,000 shares through his superannuation fund during the current trading window.
Pro Medicus said the sale was "part of a rebalancing of the superannuation fund's portfolio interests" with no further sales expected "in the foreseeable future" and Mr Kempen's combined interests in the company amounted to 629,082 shares or 0.6 percent.
Pro Medicus fell 27 cents or 0.4 percent to $60.87 with 180,604 shares traded.

EMVISION MEDICAL DEVICES

Emvision says it has appointed Prof Alan Coulthard to its clinical advisory board.
Emvision said Prof Coulthard was a professor of neuro-radiology at the University of Queensland, a specialist in diagnostic and interventional neuro-radiology at the Royal Brisbane and Women's Hospital, and was a director of research for the Department of Medical Imaging with an emphasis on mentoring junior doctors in research.
The company said Prof Coulthard's appointment was an unsalaried position.
Emvision was unchanged at $1.305.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says with the Australian Medtech Manufacturing Centre it will host four seminars supporting the Victorian medical technology manufacturing sector.
The Network said its 'Leaders at the forefront: Charting the course for Victorian Medtech Manufacturing' event would showcase Australian manufacturing capabilities and talent, and delve into the future of Victorian manufacturing and its impact on the local economy.
The Bio-Melbourne Network said it would feature speakers from the Commonwealth Scientific and Industrial Research Organisation, Invetech, SDI and Zip Diagnostics.
The Network said the event would be at Cliftons Freshwater on Southbank, Level 18/2 Southbank Boulevard, and online, on March 28, 2023 from 7:20am to 9:30pm (AEST).
For registration, go to: https://biomelbourne.org/event/medtech-manufacturing-series/.