Biotech Daily

Wednesday March 17, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ACTINOGEN UP 10%; COMPUMEDICS DOWN 5%**

*** TDM INVESTS $50m IN QBIOTICS, TAKES 12%**

*** WEHI: GENETIC DEFECT LINKED TO MACTEL EYE DISEASE**

*** UQ: 'ANAKINRA REDUCES WORST CHEMOTHERAPY SIDE-EFFECTS'**

*** FEDERAL $15m FOR PSYCHEDELICS, PTSD, MENTAL ILLNESS**

*** CRESO PHASE II PSILOCYBIN TRIAL FOR PTSD**

*** AMPLIA COMPLETES ASCENDING DOSE AMP945 TRIAL**

*** PAINCHEK WINS CE MARK, TGA APPROVAL**

*** BIONOMICS ADDITIONAL $3m PLACEMENT**

*** MEDLAB REQUESTS 'PLACEMENT' TRADING HALT**

*** MEDADVISOR TO RELEASE 15m VOLUNTARY ESCROW SHARES**

*** UNIVERSAL BIOSENSORS LOSES DIRECTOR MARSHALL HEINBERG**

*** BILL FLEMING TO REPLACE CRESO'S DR MIRI HALPERIN WERNLI**

*** PYC APPOINTS DR MICHAEL ROSENBLATT DIRECTOR**

MARKET REPORT

The Australian stock market fell 0.47 percent on Wednesday March 17, 2021, with the ASX200 down 31.9 points to 6,795.2 points. Thirteen of the Biotech Daily Top 40 stocks were up, 18 fell and nine traded unchanged.

Actinogen was the best for the second day in a row, possibly on a new CEO, Dr Steven Gourlay, up 0.3 cents or 9.7 percent to 3.4 cents, with 57.0 million shares traded. Universal Biosensors climbed six percent; Next Science was up 5.8 percent; Imugene improved 4.35 percent; Clinuvel, Dimerix and Pharmaxis were up more than three percent; Amplia, Cynata, Resmed and Resonance rose two percent or more; Cyclopharm, Starpharma and Telix were up more than one percent; with Cochlear up 0.4 percent.

Compumedics led the falls, down two cents or 4.65 percent to 41 cents, with 153,320 shares traded. Patrys fell four percent; LBT and Opthea were down more than three percent; Antisense, Medical Developments, Mesoblast, Oncosil and Optiscan shed two percent or more; Avita, Nanosonics, Polynovo, Proteomics and Volpara were down more than one percent; with CSL, Genetic Signatures, Neuren, Paradigm and Pro Medicus down by less than one percent.

QBIOTICS GROUP

Qbiotics says it has raised $50 million at 90 cents a share from Sydney's TDM Growth Partners as a cornerstone investor.

Qbiotics said that TDM would be issued 55,555,556 shares or 12.5 percent of the shares on issue, reducing to 11.8 percent at the close of the current capital raising.

Qbiotics managing-director Dr Victoria Gordon said that TDM was a long-term partner, "closely aligned with our ethical and principled approach to the business of pharmaceutical development and commercialization".

"This funding enables Qbiotics to aggressively pursue our human drug development pipeline in both oncology and wound healing, support marketing of our veterinary pharmaceutical, Stelfonta and further strengthen the Qbiotics team," Dr Gordon said.

Qbiotics said Stelfonta was approved by the US Food and Drug Administration Center for Veterinary Medicine for all non-metastatic mast cell tumors in dogs.

The company said that Stelfonta's active pharmaceutical ingredient, tigilanol tiglate, was currently in, or being planned for, four monotherapy trials including head and neck squamous cell carcinoma, melanoma and soft tissue sarcoma, with a combination trial with an anti-programmed cell death-1 (PD-1) drug being implemented.

Qbiotics is a public unlisted company.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

WEHI says it has identified a genetic defect which could prevent or delay the onset of the untreatable degenerative eye disease macular telangiectasia type 2 (Mactel).

WEHI said macular telangiectasia type 2 affected one in 1,000 Australians, with symptoms including the slow loss of vision, blindness, distorted vision and trouble reading.

In 2017, the Institute said it had discovered evidence of genes that caused Mactel and established five key regions in the genome most likely to influence a person's risk of developing the disease (BD: Feb 28, 2017).

Today, WEHI said it had identified an additional seven regions in the human genome that increased the risk of developing Mactel, including a rare DNA mutation in the phosphor-glycerate dehydrogenase (PHGDH) gene, which could help clinicians to diagnose the disease better and treat it.

The research lead investigator Prof Melanie Bahlo said that people with the PHGDH mutation were "five times more likely" to develop Mactel than people without the mutation.

The Institute said the research, 'Identification of genetic factors influencing metabolic dys-regulation and retinal support for Mactel, a retinal disorder' was published in Communications Biology, with an abstract at: https://pubmed.ncbi.nlm.nih.gov/33654266/ .

Prof Balho said that Mactel was "caused by slight changes to levels of fundamental amino acids that have no impact on any other part of the body".

"The disease is driven by two factors; metabolic amino acid on one side and then risk factors related to the cellular health of the retina on the other side, which are probably involved in transporting crucial amino acids into the retina," Prof Bahlo said.

"Both of these factors contribute to whether someone is genetically predisposed to getting Mactel in later life," Prof Bahlo said.

"This disease is really hard to diagnose, so understanding the risk factors will allow clinicians to better predict and treat the condition," Prof Bahlo said.

"By diagnosing this condition earlier, patients may be able to take mitigating steps to delay or prevent it developing," Professor Bahlo said.

WEHI said the research team would work with collaborators to identify other genes involved in Mactel to development better treatments and therapeutics.

UNIVERSITY OF QUEENSLAND

The University of Queensland says the anti-inflammatory drug anakinra could reduce the "worst and most debilitating side effects of chemotherapy" in cancer patients.
The University of Queensland said that research in mice led by Prof Irina Vetter and Dr Hana Starobova found that anakinra substantially reduced nerve symptoms for which vincristine chemotherapy was known and did not reduce the vincristine effectiveness.
The University said that vincristine was a chemotherapy for cervical, brain and lung cancers, leukaemia and non-Hodgkin's lymphomas.
The University of Queensland said the research, titled 'Vincristine-induced peripheral neuropathy is driven by canonical NLRP3 activation and IL-1β release" was published in the Journal of Experimental Medicine and an abstract was at: https://bit.ly/3rX43ie.
The University said the research initially aimed at reducing chemotherapy side effects in children with cancer and found that anakinra could be used for adult patients as well.
Dr Starobova said that chemotherapy-induced neuropathy caused tingling and numbness in hands and feet, pain, and muscle weakness leading to limping which could "persist long after treatment".
Prof Vetter said that chemotherapy "side effects are sometimes so terrible that people interrupt their treatment or end it, putting them at risk of succumbing to their cancer".
"Reducing the chemo's unpleasant symptoms ultimately will save lives and a lot of patient suffering," Prof Vetter said.
Prof Vetter said that although the research was specific to vincristine and anakinra, early findings suggested anakinra could help relieve symptoms of other chemotherapy drugs.
The University of Queensland said its researchers would work with Institute for Molecular Bioscience inflammation expert Prof Kate Schroder to test anakinra on human patients taking vincristine, and focus on how vincristine activated immune cells.

FEDERAL GOVERNMENT

The Federal Government says it will provide $15 million for "potential breakthrough combination therapies" including psychedelics for mental illnesses.
A media release from the Minister for Health Greg Hunt and the Assistant Minister for Mental Health and Suicide Prevention David Coleman said that the funding would be provided under the Medical Research Future Fund for substances including the anaesthetic ketamine, the 'magic mushroom' derived psilocybin and 3,4-methylenedioxymethamphetamine also known as MDMA or ecstasy.
Mr Hunt and Mr Coleman said the 'Innovative Therapies for Mental Illness Grant Opportunity' would accelerate clinical trials aimed at post-traumatic stress disorder (PSTD), major depressive disorder, addiction disorders and eating disorders.
They said that about four million Australians experienced a mental health disorder every year and half of all Australians would be affected by a mental illness in their lifetime.
The Government said there was evidence that substances such as ketamine, psilocybin and MDMA could offer a "promising new approach to effectively treating … mental illnesses" when used in a controlled environment in combination with psychological care.
Mr Hunt said that the "early results of trials in Australia and internationally are extremely encouraging, but more research is desperately needed before these approaches can be used by psychiatrists outside … controlled clinical trials".
"This grant opportunity will boost local research into potentially life-saving therapies and offers hope all those suffering from mental illness, including our veterans and emergency service personnel dealing with the devastating effects of PTSD," Mr Hunt said.
Applications are open at https://www.grants.gov.au/ and close on July 21, 2021.

CRESO PHARMA

Creso says it will begin an up-to 20 patient phase II trial of psilocybin for post-traumatic stress disorder in veterans and first responders in June 2021.

Earlier this week, Creso said it would acquire the Windsor, Nova Scotia-based Halucenex Life Sciences for its for its psychedelic drug program, including the mushroom-derived psilocybin, for mental illnesses (BD: Mar 15, 2021).

Today, the company said the single-arm, open-label, phase II trial would be conducted by Halucenex and enrol up-to 20 adults with treatment-resistant PTSD to determine the efficacy and safety of psilocybin.

Creso said the principal investigator of the trial was the Halifax, Nova scotia-based True North Clinical Research, a “research provider with strong ties to the veteran community”.

The company said that True North would be responsible for clinical oversight of the trial, complying Nova Scotia Ethics Committee, patient recruitment, monitoring, data capture and compilation of results and participant safety.

Creso said patients would be administered a 10-milligram dose of psilocybin on day-7 and a 25mg dose on day-14 of the trial.

The company said that following treatment on each day, subjects would be closely monitored in the clinic for incidents of adverse events and vital signs during the hallucinogenic period.

Creso said that six to seven hours post-dosing, subjects would be assessed using patient ratings to determine the subjective intensity of psilocybin’s effects.

The company said that on day-8 and day-15 of treatment the patients would return to the clinic for efficacy and safety assessments.

Creso said that patients would return to the clinic for a follow-up assessment on day-22 and would be assessed by telephone on day-36, day-90 and day-180.

The company said it had begun patient identification and expected to begin the trial in June 2021, subject to Health Canada approval of the trial.

Creso said Halucenex was responsible for obtaining the Health Canada Clinical Trial Authorization permit and expected the trial to be approved “by the end of April 2021”.

Creso was unchanged at 19 cents with 15.6 million shares traded.

AMPLIA THERAPEUTICS

Amplia says it has finished dosing in the single-ascending dose portion of the 64-subject, phase I trial of its focal adhesion kinase inhibitor AMP945.

Last year, Amplia said it had started dosing healthy volunteers in the single-ascending dose portion the safety and tolerability trial, and last month said it had begun the multiple ascending-dose portion (BD: Oct 8, 2020; Feb 17, 2021).

Today, the company said the single-ascending dose portion involved four cohorts, with the final cohort receiving the highest single dose of AMP945.

Amplia said the final cohort achieved drug exposures corresponding to the maximum allowable level specified in the trial design and established that the highest dose was safe and well tolerated.

Amplia chief executive officer Dr John Lambert said the company’s “focus is now on completing the trial in a timely manner, fully analyzing the data and preparing for future clinical studies in patients with cancer and fibrosis”.

The company said it was “on track to complete dosing and report top-line data from this trial” by July 2021.

Amplia was up half a cent or two percent to 26 cents.

PAINCHEK

Painchek says its smartphone application pain assessment software has Conformité Européenne (CE) mark and Australian Therapeutic Goods Administration clearance.
Painchek said the regulatory clearances would allow the marketing and sales of the Painchek Universal smartphone application across Europe, the UK and Australia.
The company said Painchek had previously been approved in Singapore, New Zealand and Canada (BD: Aug 6, 2019; Nov 19, 2020).
Painchek said the pain assessment software was combined with the Numeric Rating Scale pain score to allow carers to assess and manage pain for patients who cannot verbalize their pain, as well as document and manage the pain score of patients who can self-report their pain.
Painchek was up 0.7 cents or 10.1 percent to 7.6 cents with 9.9 million shares traded.

BIONOMICS

Bionomics says it hopes to raise up-to $3,065,063 in a one-for-six placement at 14.5 cents a share, run concurrently with its $20,000,000 rights offer.
In February, Bionomics said it has commitments to raise $15,991,634 at 14.5 cents a share in an underwritten placement, for a phase IIb trial of its anti-anxiety drug BNC210 for post-traumatic stress disorder (BD: Feb 9, 2021).
Last week, the company it hoped to raise $20,000,000 through a non-renounceable one-for-six rights offer at 14.5 cents a share (BD: Mar 8, 2021).
Today, Bionomics said the $3,065,063 placement would invite investors who participated in the February placement to apply for one share for every six shares held.
The company said the placement shares would be treated the same as the rights offer shares and be scaled-back in the same way if the placement and rights offer were over-subscribed.
Bionomics said that the concurrent placement share would be allocated from the shortfall under the rights offer, should there be a shortfall or from the expanded capacity.
Bionomics fell 3.5 cents or 12.7 percent to 24 cents with three million shares traded.

MEDLAB CLINICAL

Medlab has requested a trading halt “pending an announcement in relation to a placement”.
Trading will resume on March 19, 2021 or on an earlier announcement.
Medlab last traded at 29.5 cents.

MEDADVISOR

Medadvisor says that 15,008,943 shares held in voluntary escrow will be released on March 31, 2021.
Medadvisor said the shares were held by executive director Josh Swinnerton and Wavey Industries Pty Ltd.
According to the company’s most recent Appendix 2A application for quotation of securities, Medadvisor had 359,477,166 shares on issue, with none is ASX escrow.
Medadvisor was unchanged at 33.5 cents.

UNIVERSAL BIOSENSORS

Universal Biosensors says director Marshall Heinberg has resigned after 10 years on the board, effective from today.
Universal Biosensors was up three cents or six percent to 53 cents.

CRESO PHARMA

Creso says that Halucenex Life Sciences chief executive officer Bill Fleming will replace founder Dr Miri Halperin Wernli as a director.
Earlier this week, Creso said it would buy the Windsor, Nova Scotia-based Halucenex Life Sciences for $500,000 in cash, 29,251,795 shares and 17,551,077 performance shares (BD: Mar 15, 2021).
Today, the company said that Dr Halperin Wernli would resign from the company effective from today with Mr Fleming to be appointed to the board following the completion of Creso's acquisition of Halucenex.

PYC THERAPEUTICS

PYC says it has appointed Dr Michael Rosenblatt as a director and will issue him up-to 3.75 million options, subject to shareholder approval.
PYC said that as part of his appointment as a director, Dr Rosenblatt would receive 2.5 million options exercisable at 17 cents a share and vesting over three years, and would be issued a further 1.25 million options subject to shareholder approval.
The company said Dr Rosenblatt had more than 40 years' experience with bio-pharmaceutical companies, was currently a senior partner at Flagship Pioneering and was previously the chief medical officer at Merck & Co Inc.
PYC said that Dr Rosenblatt held a Bachelor of Arts from Columbia University and a Doctor of Medicine from Harvard Medical School.
PYC was up half a cent or 3.45 percent to 15 cents with 3.1 million shares traded.