Biotech Daily

Tuesday July 12, 2022

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: ONCOSIL UP 13%; AVITA DOWN 7%**

*** HYDRIX RECEIPTS UP 1% TO $9.7m; LESS THAN 2 QUARTERS CASH**

*** IMMURON TRAVELAN, PROTECTYN SALES UP 5-FOLD TO $881k**

*** IMEX, COLSUBSIDIO EXPAND RADIOLOGY CONTRACT**

*** NEUREN STARTS NNZ-2591 ANGELMAN TRIAL**

*** NEUROSCIENTIFIC ETHICS APPLICATION FOR EMTINB PHASE I TRIAL**

*** EMVISION: TWO TRIAL SITES, AVANIA CLINICAL CRO**

*** SIERRA SAGE TO TAKE UP 70% OF CRESO EGM**

*** PROVIDENCE TO SELL CRESO ANIBIDIOL IN SOUTH KOREA**

*** ZELIRA REQUESTS 'GERMAN REGULATORY RESULTS' TRADING HALT**

*** KAZIA APPOINTS NEW SCIENTIFIC ADVISORY BOARD**

*** ANTERIS APPOINTS PROF MARTIN LEON ADVISER**

MARKET REPORT

The Australian stock market edged up 0.06 percent on Tuesday July 12, 2022, with the ASX200 up 4.1 points to 6,606.3 points. Twelve of the Biotech Daily Top 40 stocks were up, 26 fell and two were untraded.

Oncosil was the best, up 0.7 cents or 13.2 percent to six cents, with 3.25 million shares traded. Nova Eye climbed 5.1 percent; Amplia, Cyclopharm and Patrys improved more than four percent; Emvision and Proteomics were up more than three percent; Resmed rose 2.1 percent; Cochlear, CSL, Impedimed, Opthea and Orthocell were up by more than one percent; with Kazia and Nanosonics up by less than one percent.

Avita led the falls, down 12 cents or 6.98 percent to $1.60, with 247,073 shares traded. Both Micro-X and Prescient lost 6.1 percent; Alcidion, Antisense, Genetic Signatures, Imugene, Mesoblast, Polynovo and Universal Biosensors fell more than four percent; Dimerix was down 3.6 percent; Clinuvel, Pro Medicus and Starpharma shed more than two percent; Actinogen, Atomo, Cynata, Immutep, Neuren, Next Science, Pharmaxis, Resonance, Telix and Volpara were down one percent or more; with Medical Developments and Paradigm down by less than one percent.

HYDRIX

Hydrix says receipts from customers for the year to June 30, 2022 were up 0.58 percent to $9,774,000 compared to the previous corresponding period.
Hydrix said that receipts from customers for its product development services and heart monitoring devices for the three months to June 30, 2022 rose 9.6 percent to $3,124,000.
The company said it had a cash burn of $7,153,000 for the year to June 30, 2022, compared to $3,248,000 for the year to June 30, 2021.
Hydrix said it had cash and cash equivalents of $1,940,000 at June 30, 2022, compared to $6,647,000 at June 30, 2021 and 1.63 quarters of funding available.
Hydrix said it did “not expect to have the current level of net operating cash flows”.
Hydrix was unchanged at 7.7 cents.

IMMURON

Immuron says that sales of Travelan and Protectyn for the year to June 30, 2022 have increased more than five-fold to $881,000, compared to the prior corresponding period.
Immuron said that sales of the over-the-counter supplement Travelan for traveller’s diarrhoea improved in North America, and “while not at pre-pandemic peak, the sales numbers in the US [were] starting to considerably pick up again”.
In 2016, Immuron said that Travelan was a natural product for the prevention of traveller’s diarrhoea, while Protectyn targeted liver and gut health (BD: May 10, 2016).
Today, Immuron chief executive officer Steve Lydeamore told Biotech Daily that North American Travelan sales were up by 494.3 percent to $630,000 compared to $106,000 in the year to June 30, 2021.
Mr Lydeamore said US Travelan sales were $561,000 for the year to June 30, 2022 compared to $4,000 the previous year, and that, for Australia, Travelan and Protectyn sales increased from $60,000 last year to $251,000 for the year to June 30, 2022.
Immuron said the improved US sales was due to increased sales in both Passport Health Travel Clinics and through Amazon’s electronic commerce channel and with travel increasing there were “positive signs as retail outlets start to restock product, once again”.
Immuron was unchanged at 9.1 cents.

IMEX HEALTH SERVICES

Imex says subsidiary Rimab SAS has a three-year contract with the Bogota, Colombia-based hospital group Colsubsidio to outsource its radiology services.
The company said the contract was an expansion of a 2019 contract which would see an expected increase of annual recurring revenue to about $7.2 million.
Imex said it would manage Colsubsidio’s radiology department and be responsible for reporting and performing magnetic resonance imaging, computerized tomography, x-ray, ultrasound, mammography, interventional radiology and nuclear medicine.
The company did not disclose the financial terms of the agreement but said it would include its artificial intelligence tools.
Imex chief executive officer Dr Germán Arango said the contract “speaks very highly of our enterprise imaging platform and of our sub-speciality radiologists”.
“We are well positioned to benefit from the trend to outsource radiology departments in hospitals as we can provide large customers such as Colsubsidio a one-stop-shop for their radiology operation as well as providing best of breed and affordable medical imaging software from the smallest to the largest facilities,” Dr Arango said.
Imex was up seven cents or 12.0 percent to 65.5 cents.

NEUREN PHARMACEUTICALS

Neuren says it has begun an up-to 20-patient, phase II trial of NNZ-2591 for Angelman syndrome at three sites in Brisbane, Melbourne, and Sydney.

Neuren said the phase II trial would enrol up to 20 children aged three to 17 years old with Angelman syndrome to examine the safety, tolerability, pharmacokinetics and efficacy of treatment with NNZ-2591 over 13 weeks.

The company said that all patients would be given oral liquid NNZ-2591 twice daily "with titration up to the target mg/kg dose during the first six weeks of treatment, subject to safety and tolerability".

Neuren said the treatment period was preceded by four weeks of observation to examine the baseline characteristics prior to treatment, against which safety and efficacy would be assessed for each child.

The company said that a follow-up assessment will be made two weeks after end of treatment.

Neuren said the primary outcome measures were safety and tolerability, including the incidence, severity and frequency of adverse events, as well as measures of standard pharmacokinetic parameters.

The company said that secondary endpoints would include the exploratory efficacy measures to be completed by clinicians and caregivers.

Neuren said the phase II trial would provide it with information to inform the design of a subsequent registration trial, with results expected by July 2023.

The company said the trial would be at hospitals in Brisbane, Melbourne and Sydney under a US Food and Drug Administration Investigational New Drug application.

Neuren chief executive officer Jon Pilcher said the company was "excited to commence this trial in Australia to assess the potential for NNZ-2591 to make a difference in Angelman syndrome, a seriously debilitating condition with no approved medicines".

Neuren fell five cents or 1.3 percent to $3.90.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says it has applied for ethics approval for an 88-volunteer phase I trial o assess the safety and pharmacokinetics of its Emtinb.

In June, Neuroscientific said it had recruited the first of 30 healthy volunteers for an "early-phase clinical trial" to assess biomarkers for proof-of-mechanism activity of Emtinb (BD: Jun 30, 2022).

Today, the company said the 88-volunteer, phase I trial was a double-blind, placebo-controlled, dose-escalation study of the safety, pharmacokinetics and pharmacodynamics of Emtinb.

Neuroscientific said the trial would be conducted by Linear Clinical Research in Nedlands, Western Australia, and included a separate study arm to investigate the concentration of Emtinb in cerebrospinal fluid samples.

The company said the trial was designed to support phase II clinical studies of Emtinb to treat patients with multiple sclerosis and Alzheimer's disease.

Neuroscientific managing-director Matt Liddelow said that "coming off the back of the recent significant milestone of recruiting the first subject for our early-phase clinical trial, we are very excited to be submitting the … [ethics] application for this important large-scale phase I clinical trial of Emtinb that will provide human safety data to support multiple phase II clinical trials in patients with neurodegenerative conditions, starting with multiples sclerosis and Alzheimer's disease".

Neuroscientific was unchanged at 20 cents.

EMVISION MEDICAL DEVICES

Emvision says it has in-principle agreements with two sites for its planned trials and has appointed the De Bilt, Utrecht-based Avania Clinical its clinical research organization.
Emvision said it had agreements with the Royal Melbourne Hospital, which was a comprehensive stroke care centre, and Sydney's Liverpool Hospital, which was "one of the largest stroke referral centres in [New South Wales]".
The company said it was awaiting ethics approvals and completion of device commissioning to begin patient enrolment.
Emvision chief executive officer Dr Ron Weinberger said that the appointment of a contract research organization and selection of sites was "a key milestone in the development of our novel portable brain scanner as we seek to fulfill our mission of improving stroke patient outcomes".
Emvision was up 6.5 cents or 3.7 percent to $1.815

CRESO PHARMA

Creso investors will vote on a resolution to issue shares to merger target Sierra Sage Herbs LLC allowing it to take up to 70.4 percent of the company.
In a series of 10 resolutions, Creso proposed to issue 12,965,455 shares and 52,999,945 options to vendors and lenders, as well as 358,069,697 shares to the Lyons, Colorado-based Sierra Sage.
In February, the company said it would buy Sierra Sage for $US21 million ($A29.5 million) in shares upfront, with additional milestone payments (BD: Feb 3, 2022).
At that time, Creso said Sierra Sage was "focused on plant-based and [marijuana] products under the Green Goo, Southern Butter and Goodgoo brands offering products in the ... first aid, beauty, sexual wellness, women's health and pet categories".
Today, Creso said an extraordinary general meeting would vote to issue 358,069,697 shares to Sierra Sage, worth about $US21 million based on a 70.66 US cents to $A1.00 exchange rate, at 8.3 cents a share; up to 1,061,420,889 milestone shares pending sales in 2022 at two cents a share, worth about $US15 million, and up to 1,662,892,726 milestone shares pending sales in 2023 at two cents a share worth about $US23.5 million.
The company said shareholders would vote to issue 4,315,790 options to lenders, Chifley Portfolios Pty Ltd, Jamber Investments Pty Ltd and SBC Global Investment Funds, exercisable at 38 cents within 12 months of issue.
Creso said the meeting would vote to issue 23,684,144 placement options.
The company said investors would vote to issue 1,965,455 shares and 6,000,000 performance shares to the co-founders of Impactive Holdings Ltd, which it acquired in 2021 (BD: Oct 25, 2021).
Creso said that the issue of performance shares was a special resolution requiring 75 percent of the vote to pass.
The company said that Impactive co-founders Brett Ayers and Kevin Tansey would be employed by Creso and the meeting would vote to issue then 500,000 options each, vesting in three equal tranches, exercisable at 13.75 cents each by October 25, 2024.
Creso said that shareholders would vote to issue 24,000,000 options to nominees of the Odeon Capital Group LLC for advisory services, half exercisable at 15 cents each and the balance exercisable at 18 cents each, by August 1, 2024.
Creso said the meeting would vote to approve 5,000,000 shares to William Lay and Noble House Consulting Ltd as part of a consultancy agreement from September 2021.
Creso said the meeting would be held virtually on August 9, 2022 at 10am (AEST).
Creso fell 0.1 cents or 2.5 percent to 3.9 cents with 1.6 million shares traded.

CRESO PHARMA

Creso says it has a letter of intent with Providence Animal Health Korea for the registration and commercialization of its marijuana Anibidiol products in South Korea.
Creso said the letter of intent with the Seoul, South Korea-based Providence Animal Health was non-binding and non-exclusive, and would see it work towards the registration, importation and commercialization of Creso's Anibidiol animal health products.
The company said it would enter a formal commercialization agreement with Providence following the completion of the initial terms under the letter of intent.
Creso said that subject to relevant approvals, it expected Providence Animal Health to begin commercializing its range in South Korea by April 2023.

ZELIRA THERAPEUTICS

Zelira has requested a trading halt regarding "an announcement in relation to receipt of German regulatory authority … results".
Trading will resume on July 14, 2022, or on an earlier announcement.
Zelira climbed 44 cents or 28.6 percent to $1.98, with 47,735 shares traded, prior to calling the trading halt.

KAZIA THERAPEUTICS

Kazia says it has appointed a new scientific advisory board consisting of Dr Priscilla Brastianos, Dr John de Groot, Dr Alan Olivero and Prof Patrick Wen.
Kazia said the board replaced a previous board including Prof Murray Brennan, Dr Karen Ferrante, Prof Peter Gunning and Dr Alex Matter.
Kazia chief executive officer Dr Garner said he was grateful for the work of the previous board, but "with paxalisib rapidly progressing towards potential commercialization, the advice and counsel of experts in the field will be essential to our success".
"Given that paxalisib has now reached a late state in its development, it seems appropriate to now reform the [advisory board] in the context of the drug's anticipated commercial market," Dr Garner said.
Kazia said Dr Brastianos was the director of the Central Nervous System Metastasis Centre at Massachusetts General Hospital, and held a Doctor of Medicine from Johns Hopkins School of Medicine in Baltimore, Maryland.
The company said Dr de Groot was a division head at the Neuro-Oncology Division at the Department of Neurological Surgery at the University of California, San Francisco, and had authored more than 135 peer-reviewed publications, as wel as led 44 clinical trials.
Kazia said Dr Olivero was a consultant specializing in drug discovery and development who previously was Genentech's head of research operations and in discovery chemistry, and held a Bachelor of Science and a Doctor of Philosophy from Stanford University in Palo Alto, California.
The company said Prof Wen was a professor of Neurology at Boston's Harvard Medical School and director of the Centre for Neuro-Oncology at Dana-Farber Cancer Institute, and held a Bachelor of Medicine and Bachelor of Surgery from the Medical College of St Bartholomew's Hospital at the University of London.
Kazia was up half a cent or 0.8 percent to 61.5 cents.

ANTERIS TECHNOLOGIES

Anteris says it has appointed Prof Martin Leon to its medical advisory board.

Anteris said Prof Leon was a professor of medicine at New York's Columbia University Medical Centre and had served on several boards, including as co-founder and chair of the Cardiovascular Research Foundation.

The company said Prof Leon had co-authored more than 2,000 papers and had been the principal investigator for more than 75 clinical trials.

Anteris fell 90 cents or 3.25 percent to $26.80.