Biotech Daily

Monday September 13, 2021

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: OSPREY UP 9%; USCOM DOWN 7%**

*** NEUREN RAISES $20m, SHARE PLAN FOR $2m MORE**

*** TELIX APPOINTS RADIUS ILLUCCIX ITALY DISTRIBUTOR**

*** IMPEDIMED: 2 ABSTRACTS BACK SOZO FOR HEART FAILURE**

*** HERAMED: 'PILOT PROGRAM WOMEN APPROVE FOETAL MONITORING'**

*** ACRUX: US FDA ACCEPTS DAPSONE GEL APPLICATION**

*** PARADIGM: 'PPS IMPROVES GRIP IN MICE WITH CHIKUNGUNYA'**

*** VGI NE1-ELITE MUSCLE SORENESS, SWELLING TRIAL**

*** CRESO: MHG ORDERS $338k MARIJUANA PRODUCTS**

*** UNIVERSAL BIOSENSORS 7.5m CEO, CFO, STAFF PERFORMANCE RIGHTS**

*** PAUL HOPPER TAKES 5.4% OF IMUGENE**

MARKET REPORT

The Australian stock market climbed 0.25 percent on Monday September 13, 2021, with the ASX200 up 18.6 points to 7,425.2 points. Seventeen of the Biotech Daily Top 40 stocks were up, 18 fell and five traded unchanged.

Osprey was the best, up 0.1 cents or 9.1 percent to 1.2 cents, with 434,576 shares traded. LBT climbed 7.4 percent; Antisense and Universal Biosensors were up more than five percent; Nova Eye and Polynovo improved four percent or more; Pharmaxis and Telix were up more than three percent; Cyclopharm, Genetic Signatures, Pro Medicus and Starpharma rose more than two percent; Dimerix and Imugene were up more than one percent; with Clinuvel, CSL, Next Science, Paradigm and Resmed up by less than one percent.

Uscom led the falls, down one cent or 6.9 percent to 13.5 cents, with 26,000 shares traded. Compumedics, Neuren, Optiscan and Prescient fell more than four percent; Alterity, Kazia, Orthocell and Proteomics lost more than three percent; Actinogen, Amplia, Avita and Opthea shed more than two percent; with Cochlear, Cynata, Immutep, Medical Developments, Mesoblast and Volpara down by less than one percent.

NEUREN PHARMACEUTICALS

Neuren says it has completed a $20 million placement at $2.05 a share and hopes to raise $2 million more through a share plan at the same price.
Neuren said the funds would accelerate the development of NNZ-2591 for a phase II trial for Prader Willi syndrome and prepare for phase III trials for Prader-Willi, Phelan-McDermid, Angelman and Pitt Hopkins syndromes.
The company said that the record date for the share plan was September 10, it would open on September 17 and close on October 1, 2021.
Neuren said Bell Potter Securities was the lead manager and bookrunner to the placement, with WG Partners co-lead manager to the placement.
Neuren fell 10 cents or 4.4 percent to $2.15.

TELIX PHARMACEUTICALS

Telix says it has appointed Bologna's Radius SRL as its exclusive distributor of the Illucix prostate cancer imaging product in Italy.
Telix said Illucix was the kit for the preparation of 68-gallium prostate specific membrane antigen-11 (68Ga-PSMA-11) and Radius was the "market leader" for the supply of gallium generators in Italy.
The company said the contract would be for three years from the national approval date, and Radius had previously supplied Illucix in Italy for "magisterial", or research and compassionate, use.
Telix said that prostate cancer was the leading cause of death in men and was the most diagnosed cancer in men in Italy, with about 39,000 new cases each year.
Telix head of Europe, Middle East and Africa Richard Valeix said Italy was "an important market and we look forward to working with Radius to bring this highly anticipated imaging agent to Italian men, living with prostate cancer, once regulatory approval is received".
Telix was up 23 cents or 3.6 percent to $6.57 with 609,538 shares traded.

IMPEDIMED

Impedimed says two abstracts supporting its Sozo device for heart failure are being presented to the Heart Failure Society of America meeting September 10 to 13, 2021.
Impedimed said the first abstract, from studies conducted at Scripps Memorial Hospital campuses, was titled 'Time to decongestion following heart failure hospitalization as measured by extracellular fluid nadir using bioimpedance spectroscopy (BIS)' and concluded that frequent monitoring of extracellular fluid using bioimpedance spectroscopy was more sensitive than weight and could help guide diuretic therapy.
The company said an abstract, titled 'Bioimpedance spectroscopy offers an objective measure of heart failure stability during a viral pandemic' addressed a concern that patients with cardiac-related congestion might be misclassified and diuretic therapy delayed when presenting with shortness of breath during the COVID-19 pandemic and bioimpedance spectroscopy might assist in triage.
Impedimed managing-director Richard Carreon said the data from the poster presentations "adds to our growing body of clinical evidence for heart failure".
"We believe, in time, our technology can aid clinicians with both diagnosis and therapies associated with managing heart failure patients, resulting in improved outcomes," Mr Carreon said.
Impedimed was unchanged at 12.5 cents with 1.5 million shares traded.

HERAMED

Heramed says up to 100 percent of an unspecified number of pregnant women approve the Heramed foetal monitoring program.

In July, Heramed said that the paid pilot program run by the San Jose, California-based Obstetrix Medical Group would evaluate the functionality and suitability of its Heracare foetal heart rate platform (BD: Jul 19, 2021).

In May, the company said Obstetrix would supply its Herabeat and Heracare at-home foetal heart-rate monitor platform to 100 pregnant women (BD: May 13, 2021).

Today, Heramed said that the program had been underway for eight weeks with 89 percent, of an unstated number of women, overall adherence to the Heracare plan.

The company said that 100 percent of the Obstetrix care team "indicated they believe the Heracare platform is safe, effective and improves the standard of care and that they enjoy offering the [product] to their patients".

Heramed said that 100 percent of the Obstetrix care team said they would recommend the platform to other care teams.

The company said 100 percent of patients surveyed "enjoyed the experience of taking [their] measurements remotely and more often" and felt supported by the care team and program, with 95 percent of women saying they enjoyed the content assigned and read.

Heramed said that 90 percent answered 'definitely' or 'yes' when asked whether Heracare "contributed to peace of mind during your pregnancy", with an overall 84 percent "patient experience score".

The company said that the second pilot program site would be in Atlanta, Georgia, and shipment of the hardware was planned for September 15.

Heramed chief executive officer David Groberman said the focus throughout the development of the monitor and platform "was to make our technology easy to use and deliver an improved holistic experience for expectant mothers while ensuring safety, accuracy and the highest level of quality".

"In parallel with the pilot [program], we have worked closely with Obstetrix and their professional team to ensure the system is effective, optimized to their needs and integrated seamlessly into their workflows," Mr Groberman said.

Heramed was up 2.5 cents or 14.3 percent to 20 cents.

ACRUX

Acrux says the US Food and Drug Administration has accepted its abbreviated new drug application for generic dapsone gel 5% for acne.

In April, Acrux said it had filed an abbreviated new drug application for the acne treatment, 7.5 percent dapsone gel, to the FDA for review, which was its fourth generic dossier today said this was its fifth generic dossier (BD: Apr 15, 2021).

Today, the company said it received FDA notification that the submission was sufficiently complete to be accepted for review, with the reference drug Aczone Gel 5%, marketed by Allergan Inc.

Acrux said the total addressable market for the product including existing generics was $US30 million.

Acrux managing-director Michael Kotsanis said the company was "pleased to achieve another milestone for our product development pipeline with this dossier submission".

"We will now work with the FDA to address any queries they may have on our dossier as we work towards approval and launch," Mr Kotsanis said.

Acrux was unchanged at 13 cents.

PARADIGM BIOPHARMA

Paradigm says pentosan polysulfate sodium (PPS) “shows significant functional joint improvement” in mice with chikungunya.

Paradigm said the research, titled ‘Pentosan polysulfate sodium prevents functional decline in chikungunya-infected mice by modulating growth factor signalling and lymphocyte activation’ was published in the US Public Library of Science (Plos) One and is at: https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0255125.

The company said the study was conducted at Griffith University’s Institute for Glycomics with Dr Lara Hererro the principal investigator and a co-author of the publication.

Paradigm said PPS showed “significant functional joint improvement” as measured by grip strength and an anti-inflammatory effect by the reduction in hind foot swelling in treated mice compared to untreated chikungunya-infected mice.

The company said chikungunya-infected, PPS-treated mice “displayed a visible reduction in the overall number of infiltrates in … structures of the hind limbs indicating that PPS protected muscle fibres from damage”.

“Furthermore, PPS treatment appeared to accelerate the inflammatory repair processes with evidence of an increase in the number of regenerating myocytes,” Paradigm said.

The company said that untreated mice had a significant reduction in grip strength but PPS-treated mice grip strength was unchanged between infection and day-6, with a significant reduction in swelling between chikungunya-infected untreated and chikungunya-infected, PPS-treated mice ($p < 0.0001$).

Paradigm was up 1.5 cents or 0.8 percent to $1.945.

VGI HEALTH TECHNOLOGY (FORMERLY AZURE HEALTH TECHNOLOGY)

VGI says it intends to run a 54-volunteer study of food additive NE1-Elite to study its efficacy and pharmaco-kinetics in patients with muscle soreness.

VGI said the trial would be conducted for subsidiary Invictus Ops by the Alexandria, Ohio-based Altipure LLC and would be led by VGI adviser Dr Jordan Moon.

The company said the first part of the study would enrol 30 volunteers in a randomized, double-blind, placebo-controlled study, with subjects administered one 40mg dose of NE1-Elite or a placebo daily for 21 days.

VGI said the primary endpoint would be a reduction in muscle soreness with a secondary endpoint a reduction in muscle swelling, improvement of muscle function and force development and body strength following high effort and heavy exercise.

The company said the second part of the study would assess the pharmaco-kinetics and bioavailability of NE1-Elite, in 24 healthy volunteers with eight per cohort receiving 40mg of a previous formulation of NE1-Elite, 40mg of the current formulation of NE1- Elite and 80mg of the current formulation of NE1-Elite.

VGI said the objective was to assess the bioequivalence between a previous and the current formulation of NE1-Elite and the upper limit of dosage using its Melt3 technology.

On the National (formerly Newcastle) Stock Exchange, VGI was untraded at 15 cents.

CRESO PHARMA

Creso says it has two purchase orders worth of CHF230,000 ($A340,933) from MHG GmbH for its marijuana-based Cannaqix hemp seed oil and 50mg lozenges.

Creso said the orders from the Zug, Switzerland-based health products distributor would broaden its European market presence.

Creso fell half a cent or four percent to 12 cents with 4.6 million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says it will grant 3,750,000 performance rights to chief executive officer John Sharman and 750,000 rights to chief financial officer Salesh Balak.
Universal Biosensors said it would issue a total of 7,500,000 performance rights, with the balance of 3,000,000 rights to be issued to other employees.
The company said it had revised Mr Sharman's long term incentive plan and the performance rights would be granted in two tranches, vesting on the achievement of "long-term value creation criteria".
Universal Biosensors said tranche one would see the issue of 5,000,000 rights, of which 2,500,000 were for Mr Sharman and 500,000 rights for Mr Balak and the remainder to other employees, pending a market capitalization equal to or greater than $300 million, or revenue exceeding $15 million in any nine-month period, or a change of control of the company.
The company said the second tranche would issue 2,500,000 rights in total, with 1,250,000 rights for Mr Sharman, 250,000 rights for Mr Balak and the remaining to be issued to other employees on a change of control of the company for more than $500 million, but a lower amount could be subject to board approval.
Universal Biosensors was up five cents or 5.9 percent to 90 cents.

IMUGENE

Executive chair Paul Hopper says he has become a substantial shareholder in Imugene with 291,196,435 shares or 5.4 percent of the company.
In May, Imugene said Mr Hopper exercised 25 million options at 4.28 cents each for a total of $1,070,000 (BD: May 25, 2021).
Last month, Imugene said an annual general meeting was held to vote on the issue Mr Hopper 94,170,967 shares at 1.55 cents per share (BD: Aug 6, 2021).
Today, Mr Hopper said the 89,730,967 shares were acquired at 1.55 cents each and were subject to escrow for 12 months from the issue date, until September 9, 2022.
Mr Hopper said the shares were held by directly and with Moreglade Pty Ltd, Kilinwate Investments Pty Ltd and Deborah Anne Coleman.
Imugene was up half a cent or 1.25 percent to 40.5 cents with 19.8 million shares traded.