Biotech Daily

Monday September 20, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ANTISENSE UP 11%; OSPREY DOWN 15%**

*** FDA HOLD ON PROTAGONIST'S RUSFERTIDE (PTG-300); 62% FALL**

*** FEDERAL $6.5m FOR RAPID HEPATITIS C TEST**

*** FEDERAL INDUSTRY MINISTERS: CHRISTIAN PORTER OUT, ANGUS TAYLOR IN**

*** VICTORIA, BURNET, DOHERTY RAPID COVID-19 ANTIBODY TEST**

*** BIOMUSE STUDY READIES ALTERITY FOR PHASE II PARKINSON'S MSA TRIAL**

*** UNIVERSAL BIOSENSORS ADDS 2 CENTRES FOR TN ANTIGEN CANCER TEST**

*** BIONOMICS PREPARES FOR BNC210 SOCIAL ANXIETY DISORDER TRIAL**

*** ADALTA: VICTORIA $4m RDTI LOAN**

*** RESAPP EXPANDS COVID-19 TRIAL TO INDIA**

*** MEMPHASYS ON-TRACK FOR SAMSON HORSE SEMEN TEST**

*** ISLAND: CURIA REPLACES CERRX FOR ISLA-101 SUPPLY**

*** CRONOS PLEADS SCHULTZ, $61m MARIJUANA DEAL TO ASX 30% QUERY**

*** ONCOSIL POTENTIAL 2nd STRIKE BOARD SPILL AGM**

*** EPSILON: VALENS 1st MARIJUANA ORDER FOR $540k**

*** ZELIRA APPOINTS ADJUPHARM GERMANY MARIJUANA DISTRIBUTOR**

*** CRESO, HALUCENEX, ACADIA UNI WORK ON PSILOCYBIN, CBD GEL CAPSULES**

MARKET REPORT

The Australian stock market fell 2.1 percent on Monday September 20, 2021, with the ASX200 down 155.5 points to 7,248.2 points. Six of the Biotech Daily Top 40 stocks were up, 27 fell and seven traded unchanged. All three Big Caps fell.

Antisense was the best on news of a presentation next Friday, up two cents or 11.4 percent to 19.5 cents, with 3.8 million shares traded. Kazia climbed 2.8 percent; with Immutep, Medical Developments, Next Science and Opthea up more than one percent.

Osprey led the falls, down 12 cents or 14.6 percent to 70 cents, with 153,961 shares traded. Pharmaxis lost 13.8 percent; Cynata and Oncosil fell eight percent or more; Alterity and Genetic Signatures were down more than six percent; Patrys, Universal Biosensors and Volpara were down five percent or more; Compumedics, Orthocell, Polynovo, Starpharma and Telix fell four percent or more; Prescient lost 3.7 percent; Clinuvel, Mesoblast, Nanosonics, Optiscan, Paradigm and Resmed shed more than two percent; Actinogen, Cochlear, Cyclopharm, Dimerix, Neuren, Nova Eye and Pro Medicus were down one percent or more; with CSL and Proteomics down less than one percent.

PROTAGONIST THERAPEUTICS

Queensland's Nasdaq listed Protagonist fell 62.0 percent to $US17.53 ($A24.08) following a US Food and Drug Administration clinical hold on its rusfertide cancer studies.

Protagonist said that dosing of patients in all ongoing clinical trials with rusfertide, or PTG-300, would be put on hold and study investigators had been contacted to facilitate patient notification.

Protagonist chief executive officer Dinesh Patel said that patient safety was "our absolute top priority".

"We are fully committed to working closely with the FDA in understanding and evaluating potential clinical risks and determining next steps for the development of rusfertide," Mr Patel said.

Last year, Protagonist said that early data from its 50-patient, phase II trial of PTG-300 for the blood cancer polycythemia vera showed a "robust clinical response" and dose-related effects (BD: Jun 1, 2020).

The company said the results showed that PTG-300 at doses ranging from 10mg to 80mg for up to 28 weeks provided dose-related control of haematocrit levels and eliminated the need for phlebotomy, or blood draining, in six of six patients received the dosing.

The company said that a seventh patient with 12 weeks of treatment had an unintended dose interruption, received a single phlebotomy and remained on the study, with eight patients then enrolled.

In 2016, the University of Queensland spin-out said it has raised $US90 million ($A117.1 million) and listed on the Nasdaq to develop peptide drugs (BD: Aug 12, 2016).

Today, Protagonist said it had notified the FDA of "benign and malignant subcutaneous skin tumors" observed in a 26-week "rasH2 transgenic mouse model" toxicology study.

"The rasH2 model is designed to detect signals related to tumorigenicity, and benign and malignant subcutaneous skin tumors were observed in this study," the company said on its website.

Protagonist said it was working with the FDA and would make all appropriate updates to clinical study documents and determine the next steps in consultation with the FDA.

On the Nasdaq on Friday, Protagonist fell 62.0 percent to $US17.53 ($A24.08) from $US46.13 ($A63.54) with 12,498,981 shares traded.

FEDERAL GOVERNMENT

The Federal Government says it will provide $6.5 million to the University of New South Wales and Adelaide's Flinders University for a rapid hepatitis C test.

A media release from Federal Health Minister Greg Hunt said the funds would help Sydney's Kirby Institute and Adelaide's International Centre for Point-of-Care Testing to improve treatment times for patients with hepatitis C, and the program that could confirm active hepatitis C infections within an hour, allowing treatment to begin immediately.

The Government said the point-of-care test would take a drop of blood from a fingertip, which could be analyzed on site, with a result ready for the patient within an hour, and if the result came back positive, treatment could begin in the same visit.

The media release said testing would be available nationally at 65 sites with a high prevalence of hepatitis C infection, including drug treatment clinics, needle and syringe programs, and prisons, and the program would include development of standard operating procedures, logistics, deployment, operator training, and external quality assurance.

The Government said Australian hepatitis C rates had declined since providing wide access to antiviral treatments "but many people living with hepatitis C are not aware they have it, so innovative methods are necessary to increase testing".

FEDERAL GOVERNMENT

Industry Minister Christian Porter has been replaced by Acting Minister Angus Taylor following Mr Porter's receipt of funds from undisclosed donors.
The then Attorney-General, Mr Porter identified himself as the alleged 'Cabinet Rapist' of a young colleague when he was a teenager, vehemently denied the accusation and sued the ABC for defamation, with the case discontinued.
In March, Mr Porter was demoted from Attorney-General to Minister for Industry Science and Technology (BD: Mar 29, 2021).
Last week, Mr Porter said that a person or persons unknown donated to a 'blind trust' to cover his defamation legal costs, and refused to disclose the donors or return the funds.
Yesterday, Prime Minister Scott Morrison said Mr Porter had resigned and Mr Taylor was appointed Acting Minister for Industry, Science and Technology from September 19, 2021.
In the six years of the Rudd-Gillard-Rudd Governments, Australia had two ministers for Industry, Senator Kim Carr as the Minister of Industry Innovation Science and Research and Greg Combet as the Minister for Industry and Innovation.
The Government of Tony Abbott re-appointed the Howard Government's Ian Macfarlane as Minister for Industry, later adding Science to the portfolio.
With the incoming Prime Minister Malcolm Turnbull saying that he would put innovation at the centre of his government, Mr Turnbull appointed senior Liberal Party MHR Christopher Pyne as the Minister for Industry Innovation and Science, who was replaced 10 months later by Greg Hunt, who in turn was replaced six months later by Senator Arthur Sinodinis.
Prime Minister Scott Morrison appointed Karen Andrews as Minister for Industry Science and Technology, until she was replaced by Mr Porter in March.
Mr Taylor is the seventh Minister for Industry since Mr Abbott's election in September 2013.

VICTORIA GOVERNMENT, BURNET INSTITUTE, DOHERTY INSTITUTE

Victoria says it has provided $500,000 to the Burnet and Doherty Institutes to develop a Covid-19 neutralizing antibody finger prick test, with results in under 20 minutes.
A media release from Victoria's Minister for Innovation and Medical Research Jaala Pulford said the Covid-19 neutralizing antibody (Nab) test would "quickly assess a person's immunity to Covid-19 and whether they need a coronavirus booster shot".
The Government said the Covid-19 Nab-Test would show the level of immunity present in individuals by accurately measuring the level of neutralising antibodies, predict a person's immunity to new and emerging variants of Covid-19 and be used at scale for large groups.
The media release said that the test could be used to determine whether a person might need a booster vaccine by analyzing their current level of immunity to the virus.
The Victoria Government said it was not a test for the severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) antigen.
The media release said that neutralizing antibodies were "a key measure of immunity to Covid-19" and part of the body's natural immune response triggered by either prior infection or vaccination against the virus.
The Government said the Burnet and Doherty Institutes developed the test inside 12 months and while at the prototype stage, the Institutes were "in commercial discussions to progress the … test so it can be used to benefit Victorians as soon as possible".
The Doherty Institute head of immunology Prof Dale Godfrey said that "other rapid tests don't measure the important neutralizing antibodies that block virus infection".
"This is the advantage of the Covid-19 Nab-Test and what makes it a valuable addition to our Covid-19 diagnostic toolkit," Prof Godfrey said.

ALTERITY THERAPEUTICS

Alterity says that initial data from its biomarkers of progression in multiple system atrophy (Biomuse) trial will aid patient selection in its planned phase II trial.
Alterity said the 44-patient study data was presented at the International Parkinson and Movement Disorder Society meeting held from September 17 to 22, 2021.
In June, Alterity said the European Medicines Agency supported its intention to use biomarkers to diagnose early-stage multiple system atrophy patients for its ATH434 phase II trial (BD: Jun 23, 2021).
The company said in June that it was conducting the Biomuse natural history study to identify biomarkers and clinical endpoints best suited to capture efficacy signals in the phase II study, with more than half of the targeted patients enrolled at the Nashville, Tennessee Vanderbilt University Medical Center.
The poster, titled 'Non-invasive imaging markers of iron accumulation in Multiple System Atrophy' was co-authored by Alterity chief executive officer Dr David Stamler and is at: https://bit.ly/3hQg5Hr.
The poster concluded that advanced quantitative magnetic resonance imaging methods "demonstrated pathological iron accumulation in the nigrostriatal, pallidal, thalamic, and dentate nucleus of the cerebellum in patients with early [multiple system atrophy]".
The poster concluded that iron concentration over time was a novel biomarker of disease progression and quantitative susceptibility mapping methods "may improve patient selection in clinical trials of disease modifying therapy in early [multiple system atrophy] and has potential for assessing treatment induced changes".
Dr Stamler said the study "accomplished what we had hoped: it has informed patient selection in phase II and it has confirmed that iron content in the brain is a promising biomarker in our target population".
Alterity said the study objective was to define the localization and extent of iron accumulation in patients with early multiple system atrophy (MSA) and had enrolled nine patients with MSA, 17 with Parkinson's disease and 18 healthy controls.
Alterity said the Biomuse study would enrol and follow patients for 12 months and was expected to provide information for the phase II study, to begin later this year.
Alterity fell 0.2 cents or 6.25 percent to three cents with 3.1 million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says the Victorian Cancer Biobank and Spain's Centre for Cooperative Research in Bioscience will study its cancer biosensor, Tn Antigen.
Universal Biosensors said that the Bilbao, Spain based Centre for Cooperative Research in Bioscience and its clinical partner the Basurto University Hospital would begin Tn Antigen studies along with Melbourne's Victorian Cancer Biobank.
The company said the trials would include 280 patients with 160 prostate patient samples to be studied at Basurto University Hospital and 120 cancer patient samples from the Victorian Cancer Biobank including 40 breast, 40 prostate and 40 colorectal.
Universal Biosensors said each patient sample would be used to determine the clinically relevant range of Tn concentrations, confirm the role of Tn in multiple cancer types and validate the performance of the company's handheld point-of-care cancer biosensor.
Universal Biosensors chief executive officer John Sharman told Biotech Daily "the Tn antigen is produced by many different cancer types, but rarely by healthy cells".
The company said the objective was for the Tn biosensor to accurately measure a patient's cancer status
Universal Biosensors fell 4.5 cents or 5.2 percent to 82.5 cents.

BIONOMICS

Bionomics says it expects to enrol 150 people in a trial of BNC210 for acute social anxiety disorder (SAD) by the end of this year (BD: May 10, 2021).
Bionomics said the study was “part of its broader pipeline expansion strategy and based on anti-anxiety signals in generalized anxiety disorder patients”.
The company said that in a previous phase IIa generalized anxiety disorder trial a single dose of the liquid suspension formulation of BNC210 “showed significant anti-anxiety signals as measured in brain imaging and behavioral studies, but without evidence of sedation or addictive potential”.
Bionomics said that “the slow absorption of the liquid suspension formulation of BNC210 and the requirement for it to be taken with food for optimal absorption, would limit its use in real world situations for the acute treatment of anxiety”.
The company said that a solid dose tablet formulation had been developed showing much improved and rapid absorption and would be used for the phase II trial.
Bionomics said the trial would compare BNC210 to placebo on anxiety levels during an anxiety-provoking behavioral task.
The company said it expected to have about 15 US sites and intended to submit an investigational new drug application (IND) application to the US Food and Drug Administration in time for the study to start by the end of this year.
Bionomics executive chair Dr Errol De Souza said that about 18 million American adults suffered from social anxiety disorder.
alone.
“There is no FDA-approved, fast-acting, as-needed treatment for [social anxiety disorder] and current standard of care FDA-approved anti-depressants and off-label use of benzodiazepines have significant potential side effects and safety concerns,” Dr De Souza said.
Dr De Souza said the tablet formulation of BNC210 was rapidly absorbed and reached maximal concentrations in the blood in about 45 to 105 minutes and might be “well-suited for the acute treatment of [social anxiety disorder] patients to better cope with anticipated anxiety-provoking social interactions and other public settings”.
Dr De Souza said he expected to report top-line data by July 2023.
Bionomics fell 0.5 cents or 2.9 percent to 16.5 cents.

ADALTA

Adalta says it has a $4.0 million Research and Development Tax Incentive loan from the Treasury Corporation of Victoria, at 0.265 percent interest a year.
Adalta said the loan was against its accrued Research and Development Tax Incentive for the period up to June 30, 2022, and would be paid in two tranches: the first of $2.4 million and the second of up to $1.6 million, not exceeding 80 percent of the company’s forecast Research and Development Tax Incentive.
The company said it had been awarded the loan through the Victorian Government’s R&D Cash Flow Loan Initiative, “designed to support innovative Victorian small to medium enterprises who are investing in research and development”.
Adalta said that repayment was timed to coincide with receipt of the Research and Development Tax Incentive, expected by October 31, 2022, and was additional to its previously announced Radium Capital Facility (BD: Jun 25, 2021).
Adalta was up 0.6 cents or 6.4 percent to 10 cents with 2.9 million shares traded.

RESAPP HEALTH

Resapp says it has recruited the first 10 of 220 patients for a pilot study on cough sounds to diagnose severe acute respiratory syndrome coronavirus (Sars-Cov-2).
Resapp said it expected recruitment to be completed by the end of October."
The company say it will use the data "to develop a smartphone-based algorithm to instantly screen for COVID-19 and monitor disease progression" (BD: Aug 9, 2021).
Resapp said the study had two arms with 120 individuals who presented for outpatient Sars-Cov-2 polymerase chain reaction (PCR) testing and 100 individuals who were Covid-19 positive and were inpatients at a study site.
The company said that inpatients would provide cough sound samples at multiple times during their hospital stay.
Resapp was up 0.1 cents or 1.2 percent to 8.2 cents with 2.6 million shares traded.

MEMPHASYS

Memphasys says its Samson stallion dismount fertility diagnostic is on-track to be field tested during the September to November Australian horse-breeding season.
In May, Memphasys executive chair Allison Coots told Biotech Daily that the test sampled the remnant of "dismount" semen left on a horse's penis after natural mating with a mare (BD: May 5, 2021).
Ms Coutts said in May that the test detected the probability of the stallion being able to fertilize a mare based on the level of mitochondrial activity in the sperm, with the result known almost instantly.
Today, Memphasys said it was on-track to conduct a field trial of its Samson prototype "during the Australian horse breeding season, September to December".
The company said a thoroughbred and standard stud farm had been arranged and testing would begin as New South Wales Covid-19 lockdown constraints lift.
Memphasys said it had identified a potential field site in the US where testing could take place during the US horse breeding season "should researchers not be able to access the [Australian] sites during the breeding season due to Covid-19 restrictions".
Memphasys fell 0.3 cents or 4.35 percent to 6.6 cents.

ISLAND PHARMACEUTICALS

Island says Curia Inc will produce two 2.5-kilogram batches of its ISLA-101 dengue fever drug previously expected from the Lubbock, Texas-based Cerrx.
In July, Island said Cerrx would supply 5kg of synthesized starting material and the Albany, New York-based Curia would manufacture active pharmaceutical ingredient for its phase IIa trial of ISLA-101 for dengue fever with Cerrx supplying the active pharmaceutical ingredient (API), and Curia processing the API to good manufacturing practice standard for a phase II trial (BD: Jul 22, 2021).
Today, Island said that "in view of an inventory error at a third-party storage facility … there is less API available to purchase than originally expected".
The company said it cancelled the Cerrx agreement at no cost and engaged Curia to produce the material for $US431,300 ($A595,776), in line with budget forecast.
Island said the change would incur a slight delay, with the original anticipated delivery of late this year being pushed back to early next year.
Island fell 2.5 cents or 6.85 percent to 34 cents.

CRONOS AUSTRALIA

Cronos 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 30.0 percent from 15 cents to 19.5 cents on Thursday September 16, 2021 and noted a "significant increase" in trading volume.
Cronos said that on September 14, it released a 156-page announcement detailing a planned $61 million merger with CDA Health Pty Ltd (BD: Sep 14, 2021).
Cronos fell one cent or 5.3 percent to 18 cents.

ONCOSIL MEDICAL

Oncosil says shareholders will vote on its remuneration report and a potential second-strike board spill, and vote on performance rights for managing director Nigel Lange.
Last year, Oncosil said its remuneration report faced 38.4 percent opposition, providing a first strike for a potential spill at this year's annual general meeting (BD: Oct 21, 2020).
Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and if passed the directors must stand for re-election at a subsequent meeting.
On Friday, Oncosil said it would vote to issue 2,841,633 performance rights to Mr Lange, with 50 percent vesting at 20 percent total shareholder return compound annual growth rate (TSR CAGR), and 100 percent vesting at 40 percent TSR CAGR.
The company said the meeting would vote on the election of Otto Buttula and Dr Roger Aston as directors, and to approve the omnibus incentive plan.
The meeting will be held on-line on October 19, 2021 at 4pm (AEDT).
Oncosil fell 0.4 cents or 8.3 percent to 4.4 cents with 7.4 million shares traded.

EPSILON HEALTHCARE

Epsilon says it has its first order, worth $540,000, under its agreement with Valens to use its Southport Queensland marijuana manufacturing plant (BD: Sep 9, 2021).
Epsilon said the orders were for white-labelled cannabis products produced at Southport, to be sold in Australia and New Zealand and it expected to complete delivery of the first two pallets of products "within the coming week" with further deliveries expected to be completed early next year, primarily for New Zealand.
The company said it expected payment for about 65 percent of the order this month, with the remainder at the time of final product delivery.
Epsilon chief executive officer Jarrod White said the order was "a significant milestone".
"Pleasingly, the receipt of our maiden order has been achieved within a week of announcing our partnership," Mr White said.
Epsilon fell one cent or 6.7 percent to 14 cents.

ZELIRA THERAPEUTICS

Zelira says it has appointed Adjupharm GmbH to market its marijuana-based Zenivol medication for insomnia in Germany.
Zelira says Adjupharm had agreed to minimum order quantities totalling more than $4 million over the five-year agreement, included at least $98,000 in the first year and would have a first right to negotiate other European markets
Zelira was up 0.3 cents or 8.1 percent to four cents with 6.9 million shares traded.

CRESO PHARMA

Creso says that subsidiary Halucenex has a collaboration with Acadia University to develop psilocybin and cannabidiol gel capsules as a vehicle for drug delivery.

Creso said that the agreement between wholly-owned Canadian subsidiary Halucenex Life Sciences and the Wolfville, Nova Scotia-based Acadia University would use Halucenex technology and experiment with novel formulations based on nano-emulsion and nano-encapsulation.

The company said that Halucenex and Acadia would work to develop drug delivery vehicles in the form of gel capsules containing cannabidiol (CBD) and psilocybin, aiming for “a quick release effect, good bio-availability of the active ingredients and rapid action”.

Creso said the project was “a key milestone” for it and Halucenex and was expected to be completed by July 2022.

Creso fell half a cent or 4.2 percent to 11.5 cents with 10.5 million shares traded.