Biotech Daily

Wednesday June 8, 2022

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: AVITA UP 6%; PRESCIENT DOWN 14%**

*** WEHI, JOHNS HOPKINS BLOOD TEST FOR COLON CANCER CHEMO**

*** LUMOS INSTO RIGHTS RAISE $8m; RETAIL FOR $3.2m MORE**

*** MICROBA, GINKGO START MICROBIOME AUTOIMMUNE DRUG PROJECT**

*** PRESCIENT CELLPRYME-M FOR CAR-T-CELL MANUFACTURE**

*** NOVA EYE ROLLS-OUT ITRACK FOR CANALOPLASTY**

*** KAZIA, ALLIANCE EXPAND PAXALISIB BRAIN METASTASES TRIAL**

*** DORSAVI TESTS ATHLETIC MOVEMENT INDEX**

*** RACE TAKES PHASE I/II ZANTRENE AML, MDS TRIAL TO EUROPE**

*** WOKE, UWA EXPAND CONSCIOUSNESS FROM PSILOCYBIN TO LSD**

*** ZELIRA: 'MARIJUANA ZENIVOL REDUCES INSOMNIA SEVERITY'**

*** RESAPP EXTENDS VOLUNTARY EXTENSION, AGAIN**

*** ONCOSIL REQUESTS 'SHORTFALL' TRADING HALT**

*** AVECHO REQUESTS 'AVEO CLEANSING, COURT ORDERS' SUSPENSION**

*** REGAL REDUCES TO 5% OF IMRICOR**

*** BILL PENG TAKES 9% OF AUDEARA**

*** ROBERT BRICE, JDB REDUCE, DILUTED TO 9.7% OF AUDEARA**

*** REGAL BELOW 5% IN ALTHEA**

*** CONTROL BIONICS LOSES CFO NEALE JAVA**

MARKET REPORT

The Australian stock market was up 0.36 percent on Wednesday June 8, 2022, with the ASX200 up 25.4 points to 7,121.1 points. Thirteen of the Biotech Daily Top 40 stocks were up, 21 fell, five traded unchanged and one was untraded. All three Big Caps were up.

Avita was the best, up 8.5 cents or 5.6 percent to $1.595, with 479,797 shares traded. Atomo, Nova Eye and Polynovo climbed four percent or more; Clinuvel, Dimerix, Proteomics and Starpharma were up more than three percent; Cochlear, Immutep, Pro Medicus and Resmed rose two percent or more; CSL and Next Science were up more than one percent; with Nanosonics and Paradigm up by less than one percent.

Prescient led the falls, down three cents or 13.6 percent to 19 cents, with 10.2 million shares traded. Antisense lost 9.1 percent; Universal Biosensors shed 6.2 percent; Cynata, Impedimed, Medical Developments and Orthocell were down five percent or more; Actinogen, Kazia and Volpara fell four percent or more; Alcidion, Amplia, Imugene and Mesoblast were down more than three percent; Cyclopharm, Opthea and Uscom shed more than two percent; Emvision, Neuren and Resonance were down more than one percent; with Telix down by 0.2 percent.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute of Medical Research says a blood test can identify which colon cancer patients require chemotherapy and which do not.

The Institute said that a study co-led with the Baltimore Maryland-based Johns Hopkins Cancer Centre trialled the blood test in more than 455 patients at 23 Australian hospitals to assess its use for cancer treatment decision-making.

WEHI said that the test “could accurately predict which patients would benefit from chemotherapy after their cancer [was] surgically removed”.

The Institute said Australian and US researchers co-designed the blood test that uses circulating tumor DNA (ctDNA) “to precisely identify the stage II colon cancer patients that need chemotherapy after surgery”.

WEHI said it was the first study to show whether patients should receive chemotherapy based on their ctDNA result, with stage II colon cancer defined as a cancer that had grown through the wall of the colon, but does not extend to the lymph nodes or other organs.

WEHI said that most patients with stage II colon cancer were cured after surgery but the cancer would recur in about 20 percent of patients, with chemotherapy offered to all stage II colon cancer patients, despite a majority not needing it.

The Institute said the study, titled ‘Circulating Tumor DNA Analysis Guiding Adjuvant Therapy in Stage II Colon Cancer’ was published in The New England Journal of Medicine, with an abstract at: https://www.nejm.org/doi/full/10.1056/NEJMoa2200075.

WEHI said that the goal of chemotherapy after colon cancer surgery was to eradicate micro-metastases, or cancer cells that have travelled from the original cancer in the bowel through the bloodstream to deposit in another site, such as the liver.

The Institute said that the cancer cell deposits were “miniscule and are not seen at surgery or on radiologic images during the initial stages [but] will gradually increase in size” and become large enough to be seen on a standard computed tomography (CT) scan if they not treated with chemotherapy.

WEHI scientist and Peter MacCallum Cancer Centre oncologist Prof Jeanne Tie said the test could be spare 100,000 people a year from unnecessary treatment.

LUMOS DIAGNOSTICS

Lumos says the institutional component of its fully-underwritten, one-for-2.55 pro-rata $11.2 million rights offer at 19 cents a share has raised $8 million.
On Monday, Lumos said the offer was underwritten by its joint lead managers, Wilsons Corporate Finance and Bell Potter Securities, with the offer price a 22.4 percent discount to the last closing price of 24.5 cents a share, on June 1, 2022 (BD: Jun 6, 2022).
Lumos fell 9.5 cents or 38.8 percent to 15 cents with 14.9 million shares traded.

MICROBA LIFE SCIENCES

Microba says it has sent its first bio-bank samples to Boston's Ginkgo Bioworks to develop microbiome-based therapies for autoimmune diseases.
Microba said Ginkgo would identify microbiome-based treatments for three autoimmune diseases including lupus, psoriatic arthritis and certain liver diseases.
The company said Ginkgo had invested $US3.5 million ($A4.9 million) in its initial public offer earlier this year (BD Apr 5, 2020).
Microba chief scientific officer Prof Lutz Krause said the partnership would accelerate the identification of microbial therapeutic leads for autoimmune diseases and help select the most promising candidates.
Microba fell 1.5 cents or 5.7 percent to 25 cents.

PRESCIENT THERAPEUTICS

Prescient says it has developed a new technique called Cellpryme-M for the manufacture of its chimeric antigen receptor (Car)-T-Cells.
Prescient said the technique was a 24-hour pre-conditioning step designed to influence immune cell gene expression to cultivate a more favorable phenotype, including up-regulated type 1 interferon and cytokine signaling, genomic stability, and anti-viral pathways, and down-regulated cell metabolism, protein folding, and mRNA splicing.
The company said that data on Cellpryme-M showed it could increase a central memory cell response by 50 percent compared to conventional Car-T-cells, double the proportion of helper T-cells elicited by conventional Car-T-cell therapy, and retain the potency of cytotoxic T-cells without increasing the risk of a cytokine storm.
Prescient said Cellpryme-M was developed with Melbourne's Peter MacCallum Cancer Centre, fitted into third-party manufacturing processes and was ready for clinical use.
Prescient managing-director Steven Yatomi-Clarke said that by producing superior cell types "Cellpryme-M truly complements the Omnicar platform, which enables control, multi-valency and many other characteristics and is agnostic to cell type".
"Cellpryme-M also opens up an entirely new business opportunity to licence Cellpryme-M to other cell therapy companies," Mr Yatomi-Clarke said.
"It requires minimal intervention into existing and emerging manufacturing process and therefore represents a relatively low implementation hurdle," Mr Yatomi-Clarke said. "This opens up real commercial opportunities for Prescient to incorporate Cellpryme-M into third party manufacturing processes," Mr Yatomi-Clarke said.
"However, in a real show of confidence, Prescient will be [its] own first customer by using it to enhance its internal Omnicar programs, to combine next-gen Car-T capabilities with superior cell phenotypes," Mr Yatomi-Clarke said.
Prescient has been developing PTX-100 and PTX-200 for a range of cancers and in 2020 acquired the Omnicar Car-T program (BD: Aug 28, 2020).
Prescient fell three cents or 13.6 percent to 19 cents with 10.2 million shares traded.

NOVA EYE MEDICAL

Nova Eye says it has begun the commercial roll-out of its Itrack Advance canaloplasty device in Europe.

Nova Eye said that the Itrack Advance was “designed to lower eye pressure and [might] reduce or eliminate the need for glaucoma eye drops”.

The company said that initial orders had been received, first shipments made and the first commercial, in-human cases completed.

Nova Eye managing-director Tom Spurling said the company was “very excited that the roll-out of the Itrack Advance has begun”.

“With a number of industry-leading features and backed by a strong [intellectual property] portfolio, we expect Itrack Advance to drive improved sales performance for the group during the 2023 fiscal year,” Mr Spurling said.

“Across most of our global markets, we have noted a marked increase in surgeon interest in canaloplasty,” Mr Spurling said.

“As an implant-free procedure that preserves the trabecular meshwork for subsequent procedures, canaloplasty offers significant utility to surgeons and their patients,” Mr Spurling said.

Nova Eye was up one cent or 4.8 percent to 22 cents.

KAZIA THERAPEUTICS

Kazia says the Alliance for Clinical Trials in Oncology-led phase II multiple therapy trial has expanded the paxalisib arm for patients with brain metastases.

In 2019, Kazia said it would conduct a 150-patient phase II trial of GDC-0084, now known as paxalisib, for brain metastases with the US Alliance for Clinical Trials in Oncology Foundation (BD: May 20, 2019).

Today, the company said the paxalisib arm of the trial had fully recruited a cohort of breast cancer metastasis patients for an initial pre-specified interim analysis, observing response to treatment among 10 patients, and had met the threshold for expansion of the study by a further 11 patients to seek more conclusive efficacy data.

Kazia fell three cents or 3.95 percent to 73 cents.

DORSAVI

Dorsavi says it is beta-testing a new version of its Athletic Movement Index wearable sensor technology.

Dorsavi said the Index would enable individual and team assessments, was designed for different levels of fitness, and would reduce assessment time by 50 percent.

The company said it aimed to gather final feedback from its existing customer base and strategic partners before a full commercial release on June 28, 2022.

Dorsavi fell 0.1 cents or 6.25 percent to 1.5 cents.

RACE ONCOLOGY

Race says it has expanded its phase Ib/IIa trial of Zantrene for acute myeloid leukaemia and myelodysplastic syndrome to include five sites in Spain and Italy.

Race said the additional sites would accelerate patient recruitment and was in response to European investigator interest in both Zantrene and extramedullary acute myeloid leukaemia and myelodysplastic syndrome.

Race was up five cents or 3.05 percent to $1.69.

WOKE PHARMACEUTICALS

Woke says the University of Western Australia will use its chemistry expertise to discover new analogues of lysergic acid diethylamide (LSD).

Woke said that LSD was “a classic hallucinogen, used recreationally since 1938, and a molecule that has shown meaningful benefit for patients with mental health disorders”.

Previously, the company said it was developing mushroom-based psilocybin for depression as well as over-the-counter mushroom-based remedies (BD: Oct 19, 2021).

Today, Woke said that LSD was “considered non-addictive with a low potential for abuse, and has been evaluated in numerous controlled studies, that have shown durable remission of psychiatric symptoms for more than 12 months after treatment for disorders such as anxiety, [post-traumatic stress disorder] and substance abuse”.

The company said that the challenge with LSD was that it was chemically complex and expensive to manufacture.

Woke said that the University of Western Australia would identify and synthesize “a library of novel chemical entities that are structurally similar to LSD”.

“The objective is to discover molecules that maintain or enhance the potency of LSD to bind with key neuroreceptors, minimize side-effects, but are simpler in structure and thus less costly for chemical synthesis,” the Woke media release said.

The company said that the first stage of the drug discovery program was expected to conclude in April 2023, with the molecules to then be pharmacologically optimized for clinical evaluation.

The University of Western Australia’s Prof Scott Stewart said that LSD “was used from the 1950s to the 1970s to achieve behavioral and personality changes, as well as remission of psychiatric symptoms in various disorders”.

“It was also observed that LSD could reduce pain, anxiety, and depression in patients with advanced cancer,” Prof Stewart said.

“However, the molecule has limitations that can be improved through medicinal chemistry approaches,” Prof Stewart said.

Woke is a private company.

ZELIRA THERAPEUTICS

Zelira says a 94-patient, longitudinal, real-world data trial of its marijuana-based Zenivol shows it “improves insomnia severity index scores and is well-tolerated”.

In 2020, Zelira and Emyria say they had an agreement for an up to 100-patient study of Zelira’s Zenivol for chronic insomnia using Emyria’s clinics (BD: Sep 30, 2020).

Today, Zelira said Zenivol reduced average insomnia severity index scores from 19.5 to 14.3, a reduction which brought average results into the sub-threshold insomnia severity class, but did not say whether the data was statistically significant.

Zelira said 44 percent of patients treated were reduced to sub-threshold insomnia, with a further 22 percent of patients being reduced to “no clinically significant insomnia”.

The company said the results provided the basis of a dosing range for Zenivol, which would be used to inform the design of a future interventional trial.

Zelira chief executive officer Dr Oludare Odumasu said the results of the study were “consistent with the previously published phase Ib/IIa clinical trial”.

“Moreover, it continues to build the story for Zenivol as an effective and safe therapeutic treatment for chronic insomnia symptoms,” Dr Odumasu said.

“Prescribers and patients can be confident in this clinically-validated cannabinoid medicine,” Dr Odumasu said.

Zelira was up five cents or 4.55 percent to $1.15.

RESAPP HEALTH

Resapp has requested a further extension to its voluntary suspension pending “an update as to the status of the proposed acquisition by Pfizer”.
On Monday, Resapp requested an extension to its suspension to follow the trading halt to consider a draft independent expert report (BD: May 31; Jun 2, 6, 2022).
In April, the company said Pfizer Australia would offer 11.5 cents a share, a 27.8 percent premium, to buy the company, valuing it at $100 million (BD: Apr 11, 2022).
Today, the company said that the suspension would continue to June 14, 2022, the day it expected the update to be made available.
Resapp last traded at 11 cents.

ONCOSIL MEDICAL

Oncosil has requested a trading halt pending an announcement on “the placement of a shortfall from its non-renounceable entitlement offer”.
In April, Oncosil said it had commitments for a $4 million placement at five cents a share and hoped to raise a further $6 million through a non-underwritten, two-for-13 entitlement offer closing on June 3, 2022 (BD: Apr 29, 2022).
The company has not disclosed the results of the rights offer.
Trading will resume on June 10, 2022, or on an earlier announcement.
Oncosil last traded at 4.9 cents.

AVECHO BIOTECHNOLOGY

Avecho has requested its AVEO options be suspended from quotation immediately, “pending the release of a cleansing prospectus and court orders in relation to the options”.
The ASX said that Avecho requested the suspension, which “only applies to the quoted options and does not apply to any other quoted securities”.
Avecho was unchanged at 1.6 cents.

IMRICOR MEDICAL SYSTEMS

Regal Funds Management says it has reduced its substantial holding in Imricor from 8,311,716 shares (5.84%) to 7,165,761 shares (5.00%).
The Sydney-based Regal said that between September 22, 2021, and May 23, 2022, it bought and sold shares, selling 29,743 shares for $42,994 or $1.446 a share on October 26, 2021 and 99,360 shares for $39,764 or 40 cents a share on March 10, 2022 “by virtue of control of Regal Funds Management Pty Ltd”.
On its website, Regal said it had completed its merger with VGI Partners, with the ASX-listed merged entity renamed Regal Partners.
Imricor fell half a cent or 2.4 percent to 20 cents.

AUDEARA

Audeara says Hsin-Chieh ‘Bill’ Peng has become substantial in the company with 10,000,000 shares, or 8.89 percent of the company.
Yesterday, Audeara said it completed a $1 million placement with the Brisbane-based Mr Peng, issuing him 10,000,000 shares at 10 cents a share (BD: Jun 7, 2022).
Audeara was up 0.8 cents or 8.25 percent to 10.5 cents.

AUDEARA

JDB Services Pty Ltd says it has reduced its substantial holding in Audeara from 11,250,726 shares (10.71%) to 11,165,726 shares (9.71%).
In a substantial shareholder notice signed by director Robert Brice, the Brisbane-based JDB Services (RAC and JD Brice Investment account) said that it sold 85,000 shares for $8,225, or 9.7 cents a share and was diluted in the placement to Bill Peng (see above).

ALTHEA

Regal Funds Management says it has ceased its substantial holding in Althea, selling 1,156,657 shares.
The Sydney-based Regal said that it sold 1,675,857 shares for $198,218 or 11.8 cents a share “by virtue of control of Regal Funds Management Pty Ltd”.
On its website, Regal said it had completed its merger with VGI Partners, with the ASX-listed merged entity renamed Regal Partners.
Althea fell half a cent or 5.05 percent to 9.4 cents with 1.8 million shares traded.

CONTROL BIONICS

Control Bionics says its chief financial officer Neale Java has resigned, with Pitcher Partners appointed to provide interim services, pending a permanent replacement.
Control Bionics fell half a cent or 2.1 percent to 23 cents.