Biotech Daily

Wednesday May 17, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: IMMUTEP UP 15%; OPTHEA DOWN 9%**

*** IMMUTEP: EFTI, KEYTRUDA 25-MONTH NSCLC OVERALL SURVIVAL**

*** CONTROL BIONICS RIGHTS FOR $2.9m**

*** VIVAZOME: EXOSOMES AID RETINA, BRAIN DAMAGE, IN MICE**

*** HYDRIX APPOINTS MK TRIMEDIC GUARDIAN MALAYSIA DISTRIBUTOR**

*** RHYTHM WINS COLOSTAT UKCA MARK**

*** CRESO ASX QUERY: 'UNEQUIVOCALLY' MERITS LISTING; RAISING HALT**

*** ANTERIS US TRANSCATHETER HEART VALVE PATENT**

*** AVECHO MANUFACTURES TPM-CBD INSOMNIA TRIAL GEL CAPSULES**

*** CORRECTION: CYCLOPHARM**

*** RESPIRI TAKES 'EQUITY RAISING' HALT TO SUSPENSION**

*** NAOS REDUCES TO 28.5% OF BTC HEALTH**

*** JENCAY CAPITAL BELOW 5% OF BLUECHIIP**

*** BIO-MELBOURNE CONNECTING WOMEN LUNCH 'SOLD-OUT', AGAIN**

MARKET REPORT

The Australian stock market fell 0.49 percent on Wednesday May 17, 2023, with the ASX200 down 35.5 points to 7,199.2 points. Eight of the Biotech Daily Top 40 stocks were up, 27 fell, three traded unchanged and two were untraded.

Immutep was the best, up 3.5 cents or 14.9 percent to 27 cents, with 4.4 million shares traded. Oncosil climbed 10 percent; Prescient improved seven percent; Compumedics, Cynata, Emvision and Pharmaxis were up more than three percent; with CSL and Proteomics up by less than one percent.

Opthea led the falls, down six cents or 8.7 percent to 63 cents, with 1.3 million shares traded. Patrys lost 7.7 percent; both Atomo and Impedimed shed 6.1 percent; Kazia and Medical Developments were down more than five percent; Antisense, Imugene and Nova Eye fell more than four percent; Avita, Micro-X and Next Science were down more than three percent; Clinuvel, Cyclopharm, Genetic Signatures, Mesoblast, Paradigm, Universal Biosensors and Volpara shed two percent or more; Actinogen, Amplia, Dimerix, Polynovo and Starpharma were down more than one percent; with Cochlear, Nanosonics, Pro Medicus, Resmed and Telix down by less than one percent.

IMMUTEP

Immutep says its 114-patient, phase II trial of eftilagimod alpha with pembrolizumab for non-small cell lung cancer has a 25.0-month median overall survival.

Yesterday, Immutep said it had “positive feedback” from the US Food and Drug Administration, “supportive of a registrational trial” to evaluate eftilagimod alpha, or efti, formerly IMP321, for first line non-small cell lung cancer (BD: May 16, 2023).

Last year, Immutep said the 114-patient, Tacti-002 phase II trial of efti, with pembrolizumab, or Keytruda, for non-small cell lung cancer had an “encouraging” overall response rate of 40.4 percent (BD: Nov 11, 2022).

Today, the company said trial results showed evidence of efti’s efficacy and safety, including safely stimulating the patient’s immune response to fight cancer.

Immutep said the initial median overall survival rate for efti with pembrolizumab in patients with programmed cell death ligand-1 (PD-L1) tumor proportion score of one percent or more was 25.0 months.

Immutep said that the pembrolizumab anti-PD-1 as a monotherapy had a 16.4-month median overall survival rate, while combinations of an anti-PD-1 with chemotherapy had a median overall survival rate of 15.8 month to 23.3-months.

The company said an oral presentation at the Society for Immunotherapy of Cancer meeting in 2022 reported an interim median duration of response of 21.6 months in the intention to treat population of 114 patients.

Immutep said the presentation showed the median duration of response included more than one-third of the 32 patients with negative PD-L1 expression and the high 48.3 percent response rate achieved in the 58 patients treated with efti in combination with pembrolizumab.

Immutep chief scientific officer Dr Frédéric Triebel said the new data added “to the body of evidence that efti’s novel activation of antigen-presenting cells provides a powerful boost to the immune system, which furthers the potential of immune checkpoint inhibitors”.

“Perhaps most importantly […] efti is generating this profound immune response across a variety of solid tumour indications, even with low PD-L1 expression, in a unique and safe manner,” Dr Triebel said.

Immutep chief executive officer Marc Voigt said that efti in combination with other immuno-oncology treatments was showing “excellent initial overall survival, which is the gold standard benchmark within oncology, across the entire intent-to-treat population of first line [non-small cell lung cancer] patients in our phase II trial”.

Immutep said more mature overall survival data and additional efficacy and safety results would be presented at a medical conference later this year.

Immutep was up 3.5 cents or 14.9 percent to 27 cents with 4.4 million shares traded.

CONTROL BIONICS

Control Bionics says it hopes to raise $2,865,000 in a one-for-three, non-renounceable rights offer at 9.5 cents a share, a 9.5 percent discount to the last closing price.

Control Bionics said the funds would be used for commercializing its products including its Neuronode and Trilogy brain-to-muscle electrical signals to control communication and movement and the Drove autonomous wheelchair module, as well as regulatory approvals for export development and the acquisition of relevant distributors.

The company said that the rights offer had a record date of May 22, would open on May 25 and close on June 16, 2023.

Control Bionics fell half a cent or 4.8 percent to 10 cents.

VIVAZOME THERAPEUTICS PTY LTD

Vivazome says two mouse studies support its exosomes for retinal degeneration and traumatic brain injury.

In January, Vivazome said it would work with the Australian National University on exosomes for age-related muscular degeneration, and in November said it would work with the University of Queensland to investigate exosome treatments for traumatic brain injury and post-traumatic brain injury epilepsy (BD: May 19, 2022, Jan 27, 2023).

Today, the company said data from its work with the two universities would be presented at the International Society of Extracellular Vesicles in Seattle, Washington from May 17 to 21, 2023, showing the functional potential of exosomes.

Vivazome said that a poster titled 'Local administration of extracellular vesicles from bone marrow-derived mesenchymal stem cells restores homeostatic communication pathways and slows the progression of retinal degeneration' was co-authored by its staff and researchers from the Australian National University and concluded that bone marrow-derived mesenchymal stem cell extracellular vesicles were "a potential therapeutic [extracellular vesicle] source to slow the progression of retinal degeneration, and can potentially be used to deliver current and future therapeutics".

The company said that the University of Queensland research was in poster titled 'Bioengineering exosomes to enhance brain targeting in a mouse traumatic brain injury model' and found that "expression of Lamp2b-RVG increases the uptake of exosomes by neuroblastoma cells and the accumulation of exosomes in the brain after systemic administration".

Vivazome chief executive officer Dr David Haylock said the company wanted to develop customized extracellular vesicle-based approaches for retinal disease and brain injury.

"These compelling new data highlight our strong progress," Dr Haylock said.

The company said the posters will be available at: https://vivazome.com/.

Vivazome is a private company.

HYDRIX

Hydrix says it has an exclusive sub-distribution agreement with Kuala Lumpur's MK Trimedic to sell the Avertix's Guardian heart attack warning device in Malaysia.

Yesterday, Hydrix said it had a distribution agreement with Avertix Medical, formerly Angel Medical (BD: May 16, 2023).

Today, the company said the four-year agreement with MK Trimedic was the first of several sub-distributor appointments in the Asia Pacific region for the Guardian device, which would "help accelerate revenues".

Hydrix fell 0.1 cents or 2.9 percent to 3.4 cents.

RHYTHM BIOSCIENCES

Rhythm says it has been granted UK Conformity Assessment (UKCA) mark certification for its Colostat blood test for colorectal cancer.

Rhythm said the UKCA was implemented post-Brexit and a legal requirement to place a device on the market in the UK, replacing the Conformité Européenne (CE) mark.

The company said Colostat met the requirements of recognized analytical, performance and safety standards and it was compliant to its intended purpose of use.

Rhythm chief commercial officer Elena Deak said the "regulatory milestone" validated the Colostat's commercial pathway with the UK having a 24 million addressable population.

Rhythm was up 33.5 cents or 95.7 percent to 68.5 cents with 7.4 million shares traded.

CRESO PHARMA

Creso has told an ASX 'financial condition' query it "unequivocally" is in a financial condition sufficient to warrant listing on the ASX, and request a capital raising trading halt.
Creso said that despite an absence of metrics in the ASX query it was in compliance with Listing Rule 12.2 requiring an entity's financial condition, including operating results, to be adequate to warrant continued quotation and listing.
In a note to the Listing Rule, the ASX said that "balance sheet, relative size of liabilities to assets and access to funds are some of the indicators of an entity's financial condition".
The ASX noted Creso's annual report for the year to December 31, 2022 and the independent auditor's report and quoted the loss of $32,782,000 and net cash outflows from operating activities of $17,306,000 for the year to December 31, 2022 and said Creso "had a deficiency between current assets and current liabilities of $5,964,000".
"As a result of these matters, there is a material uncertainty related to events or conditions that may cast significant doubt on whether the company will continue as a going concern and, therefore, whether it will realize its assets and settle its liabilities and commitments in the normal course of business and at the amounts stated," the ASX quoted the report.
The ASX noted Creso statements that to raise funds, convertible notes were preferable to a placement or rights issue which might need to be at "a significant discount to the current market price … [and] potentially more dilutive" than the SBC notes agreement, with no certainty that an acceptable level of funds would be forthcoming.
The ASX noted the company's Quarterly Activities Appendix 4C Cash Flow Report saying that at March 31, 2023, Creso had an estimated 0.45 quarters of funding.
Creso told the ASX that Listing Rule 12.2 did not set out specific metrics to form the ASX's view on a company's financial condition, but "sets out below relevant factors that unequivocally demonstrate that [its] financial condition is sufficient to warrant continued quotation of its securities and its continued listing on ASX under Listing Rule 12.2".
Creso said it had total assets at March 31, 2023 of about $38.8 million, compared to total liabilities of about $17.1 million, with cash, inventory, receivables and property plant and equipment of about $18.8 million, in excess of the total liability figure.
The company said its liabilities to assets ratio was about 0.74, but "this is skewed by several items being classified as short term debt that the company intends to resolve imminently" including: the remaining Obsidian repayment of $500,000, expected to be paid in shares; secured noteholders of $2.8 million, expected to be paid by a minimum of 75 percent in shares; an interest-free, short-term loan from a related party of $818,500 for participation in a prior placement to be settled in shares on shareholder approval; a $300,000 loan from director Jodi Scott as part of the Sierra Sage Herbs transaction, which Ms Scott indicated she would convert to equity, subject to approval; and adjusting for these items, the current ratio would be 0.94 prior to raising capital.
Creso said that if it "used only half of its placement capacity as of May 15, 2023 to raise capital, this would result in a current ratio of 1.30, considered to be very healthy".
Creso said that when its capital raising history was considered, with the major milestones in the last 18 months "that leave it in the best operational condition since listing, it is impossible to form any other view than that [it] has significant access to ongoing funding from debt and equity markets".
The company said it had made acquisitions in the last 12 months "that have materially improved its revenue profile and progression towards becoming cashflow positive".
Creso said it had a $5 million draw-down facility, at its election, as well as an offer of $2.5 million through a convertible note.
The company requested a trading halt pending a capital raising until May 19, 2023.
Creso last traded at 1.6 cents.

ANTERIS TECHNOLOGIES

Anteris says the US Patent and Trademark Office has granted an additional patent for its Duravr transcatheter heart valve, designed to mimic a healthy heart valve.
Last month, Anteris said it had been granted a US patent titled 'Prosthetic Heart Valves' that would protect its product until September 30, 2042 (BD: Apr 12, 2023).
According to the USPTO website, the additional patent was titled 'Replacement Heart Valve with Reduced Suturing'.
The company said it would protect the single-piece, tissue design with moulded leaflets used in the Duravr design until September 12, 2038.
Anteris was up 89 cents or 4.1 percent to $22.40.

AVECHO BIOTECHNOLOGY (FORMERLY PHOSPHAGENICS)

Avecho says that the Procaps Group has begun manufacturing its tocopheryl phosphate mixture oral cannabidiol (CBD) capsule for its phase III insomnia trial.
Last year, Avecho said it had approval for a 540-patient phase III trial of the marijuana-based CBD soft-gel capsule for insomnia to begin in 2023 (BD: Dec 22, 2022).
Today, the company said the Barranquilla, Colombia-based Procaps was a developer of pharmaceutical and nutraceutical medicines "ideally equipped to scale-up product manufacturing for [its] product for prescription, over-the-counter and consumer sales".
Avecho said that after the completion of its ongoing capital raise to fund the phase III trial it would be well positioned to begin the study when the product was received from Procaps by October 2023.
Last week, the company said it had raised about $2 million of a hoped-for $11 million in a one-for-one, rights offer at 0.6 cents a share and it might place the remaining $9 million shortfall (BD: May 9, 2023).
Today, Avecho chief executive officer Dr Paul Gavin said "the entitlement offer to shareholders raised sufficient capital to kick-off the manufacturing activities associated with our pivotal phase III trial".
"We can't commence the trial until the investigational product is manufactured, so raising sufficient capital to commence these activities now while we conclude raising capital was critical," Dr Gavin said.
Avecho was up 0.1 cents or 25 percent to 0.5 cents with 39.5 million shares traded.

CORRECTION: CYCLOPHARM

Last night's edition said that Cyclopharm will conduct an on-market buy-back of up-to 25 percent of the 93,696,326 shares on issue, over the next 12 months.
Cyclopharm managing-director James McBrayer told Biotech Daily: "The buy-back provision gives us the ability to buy back shares if we choose to do so."
"We do not have a plan at present to exercise this option," Mr McBrayer said.
Cyclopharm fell six cents or 2.8 percent to $2.08.

RESPIRI HEALTH

Respiri says it has requested a suspension following Monday's trading halt "to finalize an equity raising" to support its US expansion and an acquisition (BD: May 15, 2023).
Trading will resume on the release of an announcement.
Respiri last traded at 3.8 cents.

BTC HEALTH

Naos Asset Management and related parties say they have reduced their substantial holding in BTC from 84,300,587 shares (29.91%) to 80,260,587 shares (28.48%).
The Sydney-based Naos said that on May 15, 2023 it sold 4,040,000 shares on-market for $69,650, or 1.72 cents a share.
BTC Health was untraded at 1.7 cents.

BLUECHIIP

Jencay Capital says it has ceased its substantial in Bluechiip through a dilution and by selling 1,319,099 shares for $92,721 or an average of 7.03 cents a share.
Jencay said it sold the shares between June 21, 2021 and May 12, 2023.
In 2021, Jencay said it became substantial in Bluechiip with 31,591,370 shares (5.28%) buying 1,959,909 shares for 3.06 cents a share (BD: Jun 24, 2021).
Biotech Daily calculates that Jencay holds 30,272,271 Bluechiip shares or 4.4 percent of the company.
Bluechiip fell 0.1 cents or 3.85 percent to 2.5 cents.

BIO-MELBOURNE NETWORK

Bio-Melbourne says its sold-out Connecting Women Lunch this Friday will bring 590 women and men together to “encourage networking, growth and collaboration”.
Last year’s Connecting Women Lunch was also sold-out (BD: May 10, 2023).
Bio-Melbourne Network chief executive officer Jeff Malone said the Network was “looking forward to an afternoon filled with inspiration, connection and celebration”.
Mr Malone said the keynote speaker was the Walter and Eliza Hall Institute of Medical Research’s Prof Misty Jenkins.
The Network said that CSL was “the premier sponsor” with the City of Melbourne, Philips Ormonde Fitzpatrick and Radium Capital, Avatar Brokers Pty Ltd, Syneos Health, Walter and Eliza Hall Institute, Starpharma, Telix, Brandon Capital and La Trobe University.
The Network said the lunch would be held at Sofitel Melbourne, Collins Street, Melbourne on May 19, 2023.
For more details, go to: https://biomelbourne.org/event/connecting-women-lunch-2/.