Biotech Daily

Wednesday November 15, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: CYNATA UP 8%; 4D MEDICAL DOWN 8%**

*** UNISEED FUND ADDS 5 MORE UNIVERSITIES**

*** LBT RIGHTS RAISE $3.6m; $920k SHORTFALL**

*** PACIFIC EDGE INSTALLS KAISER PERMANENTE CXBLADDER**

*** EBR: VERIFICATION TESTING DELAYS FDA WISE SUBMISSION 6 MONTHS**

*** CYCLOPHARM TO START US TECHNEGAS ROLL-OUT IN Q1 2024**

*** ARGENICA WINS ARG-007 FOR HIE FDA ORPHAN STATUS**

*** MESOBLAST PLANS US REMESTEMCEL ADULT GVHD TRIAL**

*** FIREBRICK: NASODINE COLD TRIAL RESULTS 'UNRELIABLE'**

*** GOODBYE KAZIA**

*** CANN GROUP REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** EBR TO RELEASE 5.8m ASX ESCROW CDIs**

*** JM FINANCIAL, NO PLAN B TAKE 13% OF IMEX**

MARKET REPORT

The Australian stock market was up 1.42 percent on Wednesday November 15, 2023, with the ASX200 up 99.2 points to 7,105.9 points. Eighteen Biotech Daily Top 40 stocks were up, 10 fell, 10 traded unchanged and two were untraded. All three Big Caps were up.

Cynata was the best, up one cent or 7.7 percent to 14 cents, with 333,210 shares traded. Next Science and Volpara climbed more than five percent; Actinogen, Atomo, Neuren and Prescient improved more than four percent; Clinuvel, Dimerix, Emvision and Medical Developments were up more than three percent; CSL, Cyclopharm, Nanosonics, Pro Medicus, Proteomics and Resmed rose two percent or more; with Avita, Cochlear, Mesoblast and Opthea up by more than one percent.

4D Medical led the falls, down 5.5 cents or 7.6 percent to 67 cents, with 1.7 million shares traded. Amplia and Pharmaxis lost more than six percent; Compumedics was down 5.9 percent; Imugene fell 4.55 percent; Nova Eye was down 3.7 percent; Universal Biosensors shed 2.6 percent; Alcidion was down 1.4 percent; with Polynovo and Telix down by less than one percent.

UNISEED

Uniseed says five Australian universities have joined its research partner venture fund, bringing the total to 10 university partners.

Uniseed said it was “Australia’s longest-running venture fund” and that the five additional partners expanded its investible innovation network and provided “access to the majority of commercial output from Australian research organizations”.

The organization said Melbourne’s Monash University had joined as a full partner along with four New South Wales universities, including the University of Newcastle, the University of Technology Sydney, Western Sydney University and Macquarie University.

Uniseed said its existing partners were the University of Queensland, the University of New South Wales, the University of Melbourne, and the University of Sydney as well as the Commonwealth Scientific and Industrial Research and Organisation.

Uniseed said each of its existing partners spent more than $1 billion a year on research, and collectively, its expanded partners spent about $7.7 billion on research a year “making up about 60 percent of the total research spend by all research organizations in Australia”.

The organization said with the expansion it would increase its representation of Australian research and development expenditure from 43 percent to 60 percent.

Uniseed said Monash University and the four New South Wales universities would provide an additional $6.75 million to the Uniseed Fund-3, taking the total fund to $56.75 million.

Uniseed said the funds would be injected and account for previous Fund-3 investments, with $23.63 million remained investible.

The organization said the funding added to Unisuper’s $75 million commitment to the fund, with the goal of supporting exciting new developments across industries including biotechnology, pharmaceuticals, quantum computing and green energy.

Last year, Uniseed said that the $106 billion Unisuper fund has invested $75 million in the Uniseed early-stage commercialization fund manager (BD: Mar 24, 2022).

Uniseed said more than 1,000 people had been employed through funding from its start-ups, either directly or by its research partners through contract research agreements.

The organization said more than $1.2 billion had been raised by the 66 start-ups it supported, and it would appoint two investment managers for the expanded partnership.

Uniseed chief executive officer Dr Peter Devine said that “since the foundation of Uniseed in 2000, we have helped fund 66 start-ups … [and that] 17 of these have achieved commercial deals with international companies, which is a very high conversion rate”.

“This is a very significant partnership expansion as it considerably expands the reach we can offer in funding new startups and commercialising technologies developed by Australian research institutions,” Dr Devine said.

LBT INNOVATIONS

LBT says it has raised $1,030,228 from shareholders and $2,549,772 from the underwriter in its entitlement offer at 0.5 cents a share, leaving a $920,000 shortfall.

Last month, LBT said it hoped to raise $4.5 million in a four-for-one rights offer at 0.5 cents a share, with Candour Advisory Pty Ltd the underwriter (BD: Oct 13, 2023).

Today, the company said it was “exploring a partial placement of the entitlement offer shortfall, with the remainder of the shortfall to be considered over the ensuing three months from the closing date, subject to forecast capital requirements”.

LBT said chief executive officer Brenton Barnes and directors Rebecca Wilson and Damian Lismore had participated in the offer for $350,000, $67,987 and $20,800, respectively.

LBT was unchanged at 0.4 cents.

PACIFIC EDGE

Pacific Edge says it has completed the integration of its Cxbladder urine-based bladder cancer tests in the electronic medical records system of Kaiser Permanente.

Last year, Pacific Edge said the Oakland California-based Kaiser Permanente would incorporate its Cxbladder tests in its electronic medical records (EMR) system so that clinicians would be able to order Cxbladder tests and view results directly within their clinical workflow, rather than relying on a manual ordering system (BD: Jun 1, 2022).

Today, Pacific Edge said its tests would be used by urologists at Kaiser Permanente's 15 urology Southern California Permanente medical group centres.

Pacific Edge said the integration was a "significant improvement to patient access for Cxbladder with sample collection at Kaiser facilities and offers electronic management of test ordering and resulting for simpler patient care".

The company said that Kaiser Permanente' patients could have their urine samples collected at 29 separate facilities, each with its own Cxbladder collection kit, with results returned directly to their electronic medical record.

Pacific Edge chief executive officer Dr Peter Meintjes said the milestone indicated the commitment to a standard clinical pathway and was an opportunity to optimize the evaluation and management of bladder cancer.

"The patients of Kaiser Permanente [Southern California] will be among the first in the US to benefit from a standardized clinical approach to hematuria evaluation and monitoring for the recurrence of bladder cancer," Dr Meintjes said.

Pacific Edge was up one cent or 10.5 percent to 10.5 cents.

EBR SYSTEMS

EBR says verification testing has delayed its Wise cardiac pacing system pre-market approval application (PMA) to the US Food and Drug Administration by about six months.

In May, EBR said its 183-patient Wise cardiac resynchronization therapy (CRT) trial met both primary efficacy and safety endpoints and it planned to file a pre-market approval submission to the FDA by April 2024 (BD: May 22, 2023).

Today, the company said it had submitted four out of five required modules for the submission and that it expected to submit the final module by October 2024.

EBR said the delay was due to "the proposed testing schedule … from an expert consultant involved in the design verification testing required for the final module".

The company said it expected the testing schedule to strengthen its submission and place it "in a better position to receive FDA approval without further delay".

EBR said it would continue to benefit from FDA breakthrough device status, its clinical data was unchanged and the costs of the planned expanded testing were "minimal".

The company said it expected FDA approval by April 2025, and that it remained well funded through initial commercialization.

EBR chief executive officer John McCutcheon said that "as part of our commitment to ensuring the highest quality of the Wise CRT system, we have made the strategic decision to reforecast the timing of our final PMA module".

"We believe that the benefits from additional testing have the potential to demonstrate increased durability and longevity of the Wise CRT device, resulting in a more robust PMA submission," Mr McCutcheon said.

"Given we have already submitted four modules to date, we are confident in this updated timeline and remain well capitalized through to the initial commercialization phase," Mr McCutcheon said.

EBR fell 12.5 cents or 15.8 percent to 66.5 cents.

CYCLOPHARM

Cyclopharm says it expects first installations of its Technegas lung ventilation imaging device in the US to commence before April 2024.
Last month, Cyclopharm said the US Food and Drug Administration had approved Technegas for pulmonary embolism imaging (BD: Oct 2, 2023).
Today, the company said the first 20 Technegas Plus systems to be exported to the US had been manufactured and would be shipped to its third-party logistics partner.
Cyclopharm said it hoped to achieve 200 US installations by the end of 2024, with 180 additional Technegas devices currently manufactured to sub-assembly level in inventory.
The company said that because Technegas would compete with existing products, it could be used immediately using a miscellaneous product code, and it had applied to the Centres for Medicare and Medicaid Services (CMS) for a unique identifier code.
Cyclopharm said because Technegas would cost more than existing products, at $225 per patient consumable, it was applying for Medicare “pass-through status” to allow a facility to be fully reimbursed separately from the current procedure code for three years.
Cyclopharm managing-director James McBrayer said he was “very pleased” by the support and enthusiasm from the US nuclear medicine community following approval.
Cyclopharm was up five cents or 2.4 percent to $2.13.

ARGENICA THERAPEUTICS

Argenica says its ARG-007 compound for hypoxic ischaemic encephalopathy (HIE) has won US Food and Drug Administration orphan drug designation.
Argenica said the designation provided tax credits for qualified clinical trials, exemption from user fees and a potential seven years of market exclusivity after approval.
The company said it was completing the required studies to progress to clinical trials for hypoxic ischaemic encephalopathy.
Argenica managing director Dr Liza Dallimore said that “orphan drug designation for ARG-007 in HIE forms a key pillar for Argenica’s commercialization strategy”.
“The potential for extensive market exclusivity following approval of ARG-007 is an extremely compelling commercial driver for the company,” Dr Dallimore said.
Argenica was up 1.5 cents or 3.8 percent to 41 cents.

MESOBLAST

Mesoblast says it expects to contract the Blood and Marrow Transplant Clinical Trials Network for its US phase III trial of remestemcel L for graft-versus-host disease (GVHD).
According to its website, the Blood and Marrow Transplant Clinical Trials Network (BMT CTN) was a combination of the Medical College of Wisconsin, the US National Marrow Donor Program and the Emmes Company LLC.
In August, Mesoblast said the US Food and Drug Administration had provided a second complete response letter requiring more data for marketing approval (BD: Aug 4, 2023).
Today, Mesoblast said BMT CTN was responsible for about 80 percent of all US transplants and was expected to conduct the phase III adult trial “at a fraction of the cost of a traditional [contract research organization]”.
Mesoblast said it believed that the clinical studies it had performed with the potency assay data currently being generated in the paediatric phase III trial would “both support approval for the paediatric indication and provide a link between the Ryoncil product that was used in the paediatric phase III trial and available commercial inventory”.
Mesoblast was up half a cent or 1.4 percent to 36.5 cents with 1.6 million shares traded.

FIREBRICK PHARMA

Firebrick says an analysis of its Nasodine common cold phase III trial strongly indicated "major inaccuracies in the trial data … casting doubt on its reliability".
In September, Firebrick said the 500-patient Nasodine trial did not meet its primary endpoint, with sterile water placebo better impacting cold severity and last month, Firebrick said a preliminary investigation into its trial did not reveal "any systematic error or data issue that could explain or disclaim the reported results" (BD: Sep 13, Oct 3, 2023).
Today, the company said an "expert analysis" compared its two Nasodine common cold phase III trials, one in 2019 and the other in 2023, with a "human model of respiratory illness recovery … built on Australian healthcare data" from 2018 to 2022.
Firebrick said the report concluded that the 2019 trial results "conformed with the human model but showed an accelerated and amplified recovery pattern compared with both the model and the placebo".
The company said the review concluded that the 2023 trial data for both the placebo and Nasodine showed "an incongruous convergence between the placebo and active, and both placebo and Nasodine data showed a flattened recovery pattern that was inconsistent with the human model and the 2019 trial".
Firebrick said the analysis concluded that "the model outcomes strongly indicate major inaccuracies in the 2023 trial data, casting doubt on its reliability… [and] raises concerns about using the 2023 data to draw conclusions about efficacy".
The company said "no conclusions could be drawn from the modelling or the company's previous investigations as to the cause of the inaccuracies".
Firebrick said that the impact of the Covid-19 pandemic on patient reported symptoms and quality of life measures used in the study "could be a factor".
The company said it had "no concerns about the reliability or accuracy of the safety data" from the 2023 phase III trial confirming the safety profile of Nasodine, which was collected independently and was consistent with previous results.
Firebrick said the human model analysis brought investigations into the trial to a close and it was "committed to the development of Nasodine for the common cold but will now consider alternative designs that could avoid the problems experienced in the 2023 trial.
Firebrick executive chair Dr Peter Molloy said the company "firmly believe Nasodine works as a treatment for the common cold, if used at the first signs of a cold, but demonstrating that fact in a natural setting trial design is challenging".
Firebrick was up 2.9 cents or 72.5 percent to 6.9 cents with 10.2 million shares traded.

KAZIA THERAPEUTICS

The ASX says it has removed Kazia from the official list, effective from today.
Last month, Kazia said it would delist from the ASX, effective on November 14, 2023, and remain on the Nasdaq, to reduce costs (BD: Oct 11, 2023).
Yesterday, the ASX said it had suspended Kazia from quotation at its request to facilitate its removal from the official list (BD: Nov 14, 2023).
Last night, Kazia closed on the ASX at eight cents.

CANN GROUP

Cann Group says it has requested a trading halt "pending an announcement … regarding the company's capital raising activities".
Trading will resume November 17, 2023, or on an earlier announcement.
Cann Group last traded at 11 cents.

EBR SYSTEMS INC

EBR says it will release 5,785,188 Chess Depository Interests (CDIs) from ASX escrow on November 23, 2023.
According to its most recent filing, following the release from escrow, EBR would have 306,970,758 shares on issue.
The company said that 114,221,926 CDIs would be released from voluntary escrow on November 23, 2023.

IMEX HEALTH SYSTEMS

JM Financial Group Ltd and No Plan B Pty Ltd say they have increased their substantial holding in Imex from 4,737,032 shares (11.43%) to 5,521,238 shares (12.99%).
The Melbourne-based JM Financial and No Plan B said that between June 6 and November 9, 2023 they bought and sold shares, with the largest purchase 75,982 shares on October 10 for $45,589, or 60 cents a share.
Imex was untraded at 63 cents.