Biotech Daily

Thursday March 23, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: USCOM UP 7%; POLYNOVO DOWN 12%**

*** ADHERIUM: US FDA APPROVES HAILIE TEVA INHALER SENSOR 510(k)**

*** EXOPHARM $1.57m RIGHTS OFFER**

*** MAYNE UPDATES RUBRIC CONVERTIBLE NOTES TERMS**

*** BAYMATOB COMPLETES 500-MOTHER OLI POST-PARTUM TRIAL**

*** EMYRIA DOSES 50 MARIJUANA EMD-RX5 DISTRESS, PAIN PATIENTS**

*** PHARMAXIS PXS-5505, 5-AZA RESTORES MDS MICE RED BLOOD CELLS**

*** HEALTH HOUSE: COURT ORDERS CRESO ACQUISITION VOTE**

MARKET REPORT

The Australian stock market fell 0.67 percent on Thursday March 23, 2023, with the ASX200 down 47.0 points to 6,968.6 points.

Eight of the Biotech Daily Top 40 stocks were up, 28 fell, three traded unchanged and one was untraded.

Uscom was the best of the eight, up 0.3 cents or 7.1 percent to 4.5 cents with 10,000 traded. Dimerix and Pharmaxis climbed more than four percent; Cynata and Medical Developments were up more than three percent; Amplia and Neuren improved more than one percent; with CSL and Next Science up by less than one percent.

Polynovo led the falls, down 25.5 cents or 12.3 percent to $1.815, with 8.5 million shares traded.

Micro-X lost 8.7 percent; Nanosonics and Telix were down more than five percent; Atomo, Patrys and Prescient fell more than four percent; Alcidion, Avita, Clinuvel, Compumedics, Impedimed, Imugene and Kazia were down more than three percent; Actinogen, Cochlear and Opthea shed more than two percent; Emvision, Immutep, Nova Eye, Orthocell, Paradigm, Pro Medicus, Proteomics, Resmed, Starpharma and Volpara were down more than one percent; with Cyclopharm, Genetic Signatures and Mesoblast down by less than one percent.

ADHERIUM

Adherium says the US Food and Drug Administration has granted 510(k) clearance for its Haile sensor to connect to Teva Pharmaceutical Industries inhalers.
Adherium said it had FDA approval to connect its Hailie senor to Teva's pressurized metered dose inhalers (PMDI), including Pro Air and albuterol sulphate inhalers.
Last year, Adherium said it had applied to the FDA for 510(k) clearance to market Teva inhalers with its Hailie sensor and said the FDA had granted 510(k) clearance for its Haile sensor to connect to Glaxosmithkline's inhalers (BD: Aug 25, Nov 28, 2022).
Today, Adherium chief executive officer Rick Legleiter said this was "the fourth FDA 510(k) market clearance of the next-generation Hailie sensors capturing physiological data so we are now covering 79 percent [of] US top 20 branded inhalers".
"Reaching yet another major regulatory milestone, we can now move forward with the next steps for Hailie market release of Teva PMDI inhalers expanding our product portfolio on the path toward building a sustainable, cash flow positive business," Mr Legleiter said.
Adherium fell 0.1 cents or 33.3 percent to 0.2 cents with 29.5 million shares traded.

EXOPHARM

Exopharm says it hopes to raise $1.57 million in a pro-rata, non-renounceable rights issue at one cent a share, a 33 percent discount to the March 22, 2023 closing price.
Earlier this month, the company said it had subscriptions of $1,000,000 in an over-subscribed convertible note issue at $1.00 a note (BD: Mar 9, 2023).
Today, Exopharm said that the rights issue was not underwritten, had a record date of March 28, would open on March 31, and close on April 13, 2023.
Exopharm said the funds would support partnering activities, maintain its intellectual property, commercialization activities and for general working capital.
Exopharm fell 0.1 cents or 6.7 percent to 1.4 cents with 3.3 million shares traded.

MAYNE PHARMA GROUP

Mayne says it has updated conditions of the convertible notes issued to Rubric Capital "following the payment of the special dividend and … share consolidation".
Previously, Mayne said it would issue 27,950 convertible notes at $US1.00 a note, or $US27,950,000 ($A41,500,000 to New York's Rubric Capital Management to fund a $US153.1 million licencing agreement with Therapeutics MD (BD: Jan 22, 2023).
In 2022, Mayne said it would return $113 million to investors through a fully franked 2.72 cents a share dividend and a pro-rata return of 3.8 cents a share (BD: Oct 28, 2022).
At that time, the company said it intended to hold a 20-to-one share consolidation following the payment of the dividend and capital return.
In February, Mayne said it had cancelled the $113 million capital return to build on its US women's health product and pre-natal vitamin business (BD: Feb 28, 2023).
Today, Mayne said that following the payment of the special dividend and the 20-to-one share consolidation in January 2023, the notes would be convertible to shares at $5.356 a share, meaning the maximum number of shares issued to Rubric would be less than 8,943,198 shares and 9.61 percent of its issued capital.
Biotech Daily calculates that at the price of $5.356 a share, Mayne would receive about $47,899,768 on Rubric's conversion of the notes.
Mayne said the notes were issued with a 2.5 percent per annum interest rate payable quarterly over 48 months with the first payment due on March 31, 2023.
Mayne fell 10 cents or 2.8 percent to $3.50 with 954,796 shares traded.

BAYMATOB PTY LTD

Baymatob says it has completed its 500-mother pilot study evaluating its Oli artificial-intelligence, labor-monitoring device to predict post-partum haemorrhage.

Last year, Baymatob said it raised $4,215,000 for clinical trials of its Oli wearable device to identify mothers-to-be who were at high risk of developing post-partum haemorrhage, well before giving birth (BD: Mar 21, 2022).

Baymatob said at that time that that post-partum haemorrhage, or heavy bleeding after childbirth was a “serious complication of pregnancy and ... the world’s leading cause of preventable maternal death”.

In 2021, Baymatob said it had US Food and Drug Administration breakthrough device designation for the Oli monitor (BD: Aug 17, 2021).

Today, the company said it had completed the study with results expected for publication in 2023.

Baymatob said that “current clinical evidence suggests that more than 80 percent of mothers with [post-partum haemorrhage] could have clinical attention before bleeding starts using Oli, improving health outcomes and decreasing risk”.

Baymatob said the study was conducted at two Sydney sites, the Royal North Shore Hospital and the Royal Hospital for Women and was led by Prof Michael Nicholls, Prof Andrew Bisits and Michelle de Vroom.

Baymatob chief executive officer Tara Croft said the completion of its 500-patient pilot study put it on-track to a larger pivotal study in Australian and the US and was a “definitive step toward regulatory approval”.

“The early results we have seen are already a strong indication of Oli’s potential impact and its potential for saving the lives of both mothers and children,” Ms Croft said.

“Completing this Australian study paves the way for a larger pivotal trial in 2023, which will be critical in a successful [US Food and Drug Administration] and [Australian Therapeutic Goods Administration] submission,” Ms Croft said.

Baymatob is a private company.

EMYRIA

Emyria says it has dosed 50 patients in its 300-patient phase III trial of marijuana-based EMD-RX5 for distress and anxiety in adults with a chronic health condition.

In January, Emyria said it had dosed the first of 300 patients in the multi-site, parallel-arm, randomized, double blind, placebo-controlled trial of people aged 18 to 70 years with symptoms of stress and a background of chronic pain (BD: Jan 30, 2023).

At that time, the company said participants would be randomized to one month of treatment with either 50mg EMD-RX5, 150mg EMD-RX5 or placebo.

Previously, Emyria said that EMD-RX5 was a solid capsule of cannabidiol (CBD) without tetrahydrocannabinol (THC) or impurities and had shown a high bio-availability in phase I trials, with the 150mg dose the maximum allowable for over-the-counter sales.

Today, Emyria said that more than 100 patients had been screened, with 1,830 patients registered for pre-screening.

The company said that the trial would support the registration of EMD-RX5 as an over-the-counter medicine, and that it was “on track” to complete recruitment by July, with “clinical efficacy” results expected in August 2023.

Emyria fell half a cent or 2.9 percent to 17 cents.

PHARMAXIS

Pharmaxis says a pre-clinical study shows “significantly restored” formation of red blood cells when myelodysplastic mice were treated with PXS-5505 and 5-azacytidine (5-AZA).

Pharmaxis said the study, ‘Inhibition of lysyl oxidases synergizes with 5-azacytidine to restore erythropoiesis in myelodysplastic and myeloid malignancies,’ was published in Nature Communications, at: https://www.nature.com/articles/s41467-023-37175-8.

The company said that the study was a pre-clinical collaboration with Germany’s University of Heidelberg investigating the role of lysyl oxidase enzymes in myelodysplastic syndrome and the effect of combining the standard-of-care, 5-azacytidine (5-AZA) and decitabine, with its pan-lysyl oxidase inhibitor, PXS-5505.

In 2021, Pharmaxis said data from the first dose of PXS-5505 for myelofibrosis in its dose-escalation phase Ic/IIa trial showed “strong” inhibition of two target enzymes, LOX and LOXL2, which was “highly statistically significant” (BD: Jun 29, 2021).

In 2022, Pharmaxis said interim data from its 24-patient phase II trial of PXS-5505 for myelofibrosis suggested an “excellent safety profile with encouraging signs of clinical activity” (BD: Oct 19, 2022).

At that time, the company said two of six patients had “clinically important improvement in symptoms” five of six patients had stable or improved bone marrow fibrosis scores, with five of six having stable or improved platelet or haemoglobin scores.

Today, Pharmaxis said the pre-clinical study concluded that the “significant increase” in red blood cell production made a “strong case” for trialing PXS-5505 with the standard-of-care in myelodysplastic syndrome patients, especially those who were anaemic.

Pharmaxis said that all LOX and LOXL genes, except for LOXL1, were significantly overexpressed in bone marrow cells derived from patients with myelodysplastic syndrome and other related haematological malignancies when compared to healthy controls, leading to a “corresponding increase in lysyl oxidase activity”.

The company said that formation of red blood cells from bone marrow taken from patients was significantly restored when treated with PXS-5505 combined with 5-AZA in 20 of 31 cases (65%), compared to nine of 31 cases (29%) when treated with 5-AZA alone.

Pharmaxis said that the mouse study showed normalization of spleen sizes, a reduction of bone marrow cells with severe mutations, as well as “significant reduction” of disease burden.

Study lead author, Heidelberg University’s Prof Daniel Nowak said the study was “one of the first published showing that re-modelling the extracellular matrix and bone marrow micro-environment can induce outstanding improvements of haematopoiesis in these diseases”.

“The significant boost in erythropoiesis achieved by adding PXS-5505, allied to its favorable safety profile makes the combination of 5-AZA and PXS-5505 interesting for both high and low risk MDS as well as chronic myelomonocytic leukemia, myelofibrosis and low blast acute myeloid leukemia, filling a significant gap in the current treatment landscape of these diseases,” Prof Nowak said.

Pharmaxis chief executive officer Gary Phillips said “this is a compelling body of research gathered over a multi-year collaboration between Heidelberg University and Pharmaxis that extends the potential for PXS-5505 to treat haematological malignancies beyond myelofibrosis where we have recently reported encouraging preliminary phase 2 clinical trial data”.

“There will be updates [by June 30, 2023] as more patients complete six months treatment and we get feedback from the [US Food and Drug Administration] on progressing the development of PXS-5505 in myelofibrosis,” Mr Phillips said.

Pharmaxis was up 0.2 cents or 4.4 percent to 4.7 cents.

CRESO PHARMA, HEALTH HOUSE INTERNATIONAL

Health House says the Supreme Court of Western Australia has orders it to convene a meeting to vote on the proposed Creso acquisition and publish a scheme booklet.

In 2022, Creso said it had a non-binding agreement to acquire the Perth-based medical marijuana distributor Health House International for up to $4,630,388 in shares and options (BD: Aug 1, 2022).

In a separate announcement, Health House said that Creso would acquire it for a 67 percent premium to its market capitalization based on the closing price of Health House shares on July 27, 2022 of 12 cents a share and Creso's share price of 4.9 cents a share at the same date.

Today, Health House said that the meeting would be held at Pathways Corporate, Level 3, 101 St Georges Terrace, Perth, on May 2, 2023 at 1.30pm (AWST).

The company said that if shareholders approved the acquisition, a second court hearing would be held on May 4, 2023.

Creso was unchanged at one cent with 1.1 million shares traded.

Health House was up 0.1 cents or 14.3 percent to 0.8 cents.