Biotech Daily

Thursday February 9, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: GENETIC SIGNATURES UP 5%; USCOM DOWN 8%**

*** ANTERIS RAISES $35m**

*** CARDIEX RAISES $4.5m**

*** MESOBLAST: REXLEMESTROCEL-L FOR BACK PAIN US RMAT STATUS**

*** ARGENICA 'ARG-007 INHIBITS AMYLOID-BETA, IN-VITRO'**

*** DIMERIX DMX-200 FSGS TRIAL REVIEW: 'NO SAFETY CONCERNS'**

*** GENETIC TECHNO: 'GENETYPE BEATS OTHER BREAST CANCER TESTS'**

*** CLARITY RECRUITS 'COBRA' CU-64 PROSTATE CANCER TRIAL**

*** ANTERIS: US FDA 'EXPANDED APPROVAL' FOR DURAVR THV STUDY**

*** TOTAL BRAIN WIND-UP, LIQUIDATORS EGM**

*** MERCHANT REDUCES TO 10.55% IN HEXIMA**

MARKET REPORT

The Australian stock market fell 0.53 percent on Thursday February 9, 2023, with the ASX200 down 39.8 points to 7,490.3 points. Five of the Biotech Daily Top 40 stocks were up, 22 fell, 10 traded unchanged and three were untraded. All three Big Caps fell.

Genetic Signatures was the best, up 3.5 cents or 4.7 percent to 77.5 cents, with 23,394 shares traded. Paradigm improved 4.1 percent; Dimerix was up 3.7 percent; Resonance rose 1.8 percent; with Neuren up by 0.4 percent.

Uscom led the falls, down 0.4 cents or 8.2 percent to 4.5 cents, with 41,161 shares traded.

Atomo lost 7.4 percent; Oncosil, Opthea and Pharmaxis fell more than four percent; Alcidion, Impedimed, Imugene and Universal Biosensors were down more than three percent; Antisense, Avita, Medical Developments, Proteomics and Volpara shed more than two percent; Actinogen, Clinuvel, Mesoblast and Telix were down more than one percent; with Cochlear, CSL, Nanosonics, Polynovo, Pro Medicus, Resmed and Starpharma down by less than one percent.

ANTERIS TECHNOLOGIES

Anteris says it has raised $35 million in a placement at $24.00 a share, to “various sophisticated and professional investors” with one option for each new share acquired.
Anteris said the unlisted options would be exercisable at $29.00 within two years.
The company said its two largest holders, Perceptive Advisors and L1 Capital “corner-stoned” the placement, subscribing “beyond their existing pro-rata shareholding”, with managing-director Wayne Paterson buying $100,008 in shares, subject to approval.
Anteris said that funds would be used for the development of its Duravr transcatheter heart valve and for general working capital.
Anteris fell 57 cents or 2.4 percent to $23.47.

CARDIEX

Cardiex says it has raised $4.5 million in a placement to sophisticated investors at 30 cents a share, with an attaching option for each two shares acquired.
Cardiex said the placement was at a 13 percent discount to the last closing price and the unlisted options were exercisable at 50 cents each within one year from issue.
The company said the placement was “corner-stoned” by directors with $450,000 received, including support from C2 Ventures, which was controlled by Cardiex chief executive officer Craig Cooper, chair Niall Cairns and executive director Jarrod White, subject to shareholder approval.
Cardiex said that MST Financial Services Pty Ltd was lead manager to the placement.
Cardiex said that funds would be used to support product development, expand its US executive team and provide general working capital.
Cardiex fell 1.5 cents or 4.35 percent to 33 cents.

MESOBLAST

Mesoblast says the US Food and Drug Administration has granted rexlemestrocel-L regenerative medicine advanced therapy (RMAT) designation for chronic low back pain.
Mesoblast said the RMAT designation was granted to rexlemestrocel-L, formerly known as MPC-06-ID, for chronic low back pain associated with disc degeneration, in combination with hyaluronic acid as delivery agent for injection into the lumbar disc.
The company said RMAT designations aimed to “expedite the development of regenerative medicine therapies intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition where preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for the disease or condition”.
Mesoblast said that an RMAT designation provided “all the benefits of breakthrough and fast track designations, including rolling review and eligibility for priority review on filing of a biologics license application”.
In 2021, Mesoblast said that a 404-patient, phase III, randomized, controlled trial of rexlemestrocel-L, with and without hyaluronic acid compared to placebo, “did not reach statistical significance across the entire study” (BD: Feb 11, 2021).
In 2022, Mesoblast said that 36-month follow-up of the phase III trial of rexlemestrocel-L for chronic lower back pain showed durable pain reduction (BD: Jan 16, 2022).
Today, Mesoblast said that data from its phase III trial of rexlemestrocel-L, combined with hyaluronic acid “formed the basis for [the] FDA’s determination that Mesoblast’s allogeneic cell therapy has the potential to address unmet medical needs for patients suffering from [chronic low back pain] due to disc degeneration”.
Mesoblast fell 1.5 cents or 1.3 percent to $1.18 with 8.9 million shares traded.

ARGENICA THERAPEUTICS

Argenica says pre-clinical data shows ARG-007 “significantly inhibited the aggregation of human recombinant amyloid-beta” in-vitro.

Argenica said that the Graz, Austria-based contract research organization QPS performed the study to determine the effects of 2.5μM, 7.5μM and 25μM ARG-007, compared to controls, in inhibiting human recombinant amyloid-beta aggregation.

The company said that amyloid-beta aggregation was “thought to be one of the main causes of Alzheimer’s disease, with the amyloid-beta accumulation in senile plaques causing memory loss and confusion”.

Argenica said that amyloid-beta aggregation was assessed at four hours, 10 hours and 16 hours post administration of ARG-007.

Argenica said that ARG-007 had a “positive effect in inhibiting [amyloid-beta] aggregation at the 10-hour and 16-hour post administration time points, compared to the vehicle controls” and that at 16 hours, when amyloid-beta had reached maximum aggregation, all three concentrations of ARG-007 “showed a large significant reduction in [amyloid-beta] aggregation compared to the control”.

The company said that at 16 hours, 25μM ARG-007 showed a reduction greater than 50 percent in amyloid-beta aggregation.

Argenica managing-director Dr Liz Dallimore said the study had provided “extremely encouraging data showing a potential new indication for ARG-007”.

“It is well recognized that [amyloid-beta] aggregation in the brain plays a key role in initiating Alzheimer’s disease and therefore a safe therapeutic drug that can reduce [amyloid-beta] aggregation is a huge opportunity,” Dr Dallimore said.

Dr Dallimore told Biotech Daily that pharmaceutical companies had spent billions of dollars developing monoclonal antibodies to target amyloid beta.

“Targeted monoclonal antibodies to amyloid beta might not be the best approach,” Dr Dallimore said. “However, a pluri-functional drug such as ARG-007 which may target more than just amyloid beta aggregation, such as Tau tangles and inflammation, may be a better approach.”

“Our in-vivo data in a mouse model will give us greater insight,” Dr Dallimore said.

Argenica was up six cents or 14.8 percent to 46.5 cents.

DIMERIX

Dimerix says a review of its phase III study of DMX-200 for focal segmental glomerulosclerosis (FSGS), has found no concerns and recommended the trial continue.

Last year, Dimerix said it had recruited 72 patients in the first part of its 144 patient, multi-centre, randomized, double-blind, placebo-controlled trial, to study the efficacy and safety of its DMX-200 in patients with FSGS (BD: May 31, Dec 15, 2022).

At that time, the company said the trial had two interim analysis points designed to capture evidence of proteinuria and kidney function to support accelerated marketing approval.

Dimerix said the first part of the trial would conclude once 72 patients completed 35 weeks of treatment, expected in the first half of 2023, with the second part continuing after patients showed a minimum of six weeks stable dosing of an angiotensin receptor blocker prior to randomization and dosing with 120mg DMX-200 twice daily or placebo.

Today, the company said it expected data for the first part of the trial by the end of 2023.

Dimerix chief medical officer Dr Ash Soman said the “positive recommendation is a key milestone, which enables us to continue patient enrolment as planned and to complete the trial as soon as possible”.

Dimerix was up half a cent or 3.7 percent to 14 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says its Genetype breast cancer test outperforms 5-year and remaining lifetime risk prediction compared to commonly used clinical models.

Genetic Technologies said that an article titled, 'Validation of a breast cancer risk prediction model based on the key risk factors: family history, mammographic density and polygenic risk,' was published in Breast Cancer Research and Treatment and was available at: https://link.springer.com/article/10.1007/s10549-022-06834-7#Fun.

The linked article did not refer to the Genetype model risk factors for breast cancer, but instead referred to a "simple breast cancer risk prediction model", or 'Brisk,' which included factors such as "polygenic risk score, mammographic density and clinical factors".

Genetic Technologies chief executive officer Simon Morriss told Biotech Daily that Genetype and Brisk were "completely interchangeable" terms.

The article said that the Brisk model outperformed 5-year and remaining lifetime risk prediction compared to the Gail and IBISv7 tests, respectively.

The article said that Brisk performed better than "two commonly used clinical risk models and no worse compared to [the Rosner] model with more risk factors".

Genetic Technologies said that the Genetype model had "equivalent performance to the Rosner model without the need to collect a substantially larger number of risk factors," as the Rosner model used more complex factors to assess risk.

Genetic Technologies said that its objective was "to create a model that performs well, but takes less time to implement in the clinic".

The company said that the use of Genetype could "improve uptake of risk-reducing medication, potentially resulting in a significant reduction in the incidence of breast cancer".

The article said that the study was fully funded by Genetic Technologies, which "had no role in the conceptualization, design, data analysis, decision to publish, or preparation of the manuscript", but several authors were either employed by or related to Genetic Technologies, including lead author Richard Allman, its then scientific advisor.

Mr Morriss said the publication of the data was "a critical step to support our reimbursement strategy".

"The building list of supportive clinical data along with our budget impact model shows US payers and insurers that the introduction of the easy-to-implement Genetype risk assessment test for breast cancer enables doctors to have increased visibility of at-risk women," Mr Morriss said.

"The result being early detection in women and a reduction in the cost of expensive health care," Mr Morriss said.

Genetic Technologies was unchanged at 0.4 cents with 87.6 million shares traded.

CLARITY PHARMACEUTICALS

Clarity says it has fully recruited its 50-patient, phase I/II, non-randomized, open-label 'Cobra' trial of copper-64-SAR-bis-PSMA prostate cancer imaging trial.

Last year, Clarity said the multi-centre, single arm trial had opened for recruitment in the US (BD: Mar 28, 2022).

Today, Clarity said the study's primary objectives were to investigate the safety and tolerability of Cu64-SAR-bisPSMA as well as its ability to correctly detect the recurrence of prostate cancer.

Clarity fell 5.5 cents or 6.6 percent to 77.5 cents with 1.5 million shares traded.

ANTERIS TECHNOLOGIES

Anteris says the US Food and Drug Administration has granted “expanded approval” for a feasibility study of its Duravr transcatheter heart valve for severe aortic stenosis.

Last year, Anteris said the FDA had “conditionally approved” its Duravr transcatheter heart valve (THV) system for a 15-patient early feasibility study to evaluate the safety and feasibility of the system in the treatment of 15 patients with symptomatic severe native aortic stenosis (BD: Nov 28, 2022).

At that time, the company said the FDA had categorised Duravr THV as a Centers for Medicare and Medicaid Services (CMS) category B device, which allowed the device to be sold during the study pending CMS approval, and had accepted the investigational device exemption application for the study.

Today, Anteris said the approval would remove previous conditions placed on the study, allowing it to “accelerate certain activities related to study execution” and would finalize the reimbursement level under the category B designation previously granted by the FDA.

Anteris chief executive officer Wayne Paterson said “the Duravr THV clinical program continues to gather significant momentum with the removal of conditions by the FDA further paving the way for our ground-breaking technology”.

“We are excited to continue building our remarkable real-world evidence base amongst patients receiving Duravr in the United States as we progress on our path to regulatory approval,” Mr Paterson said.

TOTAL BRAIN

Total Brain says an extraordinary general meeting will vote to voluntary wind-up, appoint liquidators and approve remuneration of liquidators.

Total Brain said the resolution to wind-up the business required a 75 percent majority.

In February, the company said shareholders voted overwhelmingly to delist from the ASX and approved a capital return to shareholders (BD: Feb 1, 2023).

Last year, Total Brain said it had completed the sales of the company and its subsidiaries to Sondermind Inc for $US10 million (BD: Nov 1, 2022).

The meeting will be held at Level 3, 62 Lygon Street, Carlton, Victoria on March 10, 2023 at 9am (AEDT) and virtually at: https://web.lumiagm.com/384-538-323.

Total Brain was up 0.1 cents or 20 percent to 0.6 cents with 10.3 million shares traded.

HEXIMA

Merchant Group Australia Pty Ltd says it has reduced its holdings in Hexima from 19,686,348 shares (11.79%) to 17,629,660 shares (10.55%).

Last week at a Hexima extraordinary general meeting, Perth’s Merchant Group failed to replace three Hexima directors with Chris Mews with more than 67.5 percent opposing the spill resolutions (BD: Jan 31, 2023).

Today, Merchant said it bought and sold shares between January 23, and February 8, 2023, with the single largest sale of 1,000,000 shares for $16,000 or 1.6 cents a share.

Hexima was up 0.1 cents or 6.25 percent to 1.7 cents.