



Biotech Daily

Tuesday March 12, 2024

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: MESOBLAST UP 23%; CYNATA DOWN 5%**
- * **DIMERIX RAISES \$20m FOR PHASE III DMX-200 FSGS TRIAL**
- * **BLUECHIIP RIGHTS RAISE \$1.3m; TOTAL \$2.1m**
- * **SNOW FOUNDATION \$16m FOR 2 QUEENSLAND UNI, ANU RESEARCHERS**
- * **ANTERIS: FULL 30-DAY DURAVR HEART VALVE DATA**
- * **ARTRYA, TANNER VALIDATE SALIX CORONARY ANATOMY SOFTWARE**
- * **RECCE STARTS PHASE I/II R327 20-MINUTE INFUSION COHORT**
- * **MELODIOL TELLS ASX QUERY: ‘GOING CONCERN, TRACK RECORD’**
- * **NZ HIGH COURT ORDERS VOLPARA, LUNIT SALE MEETING**
- * **PINCHEK REQUESTS ‘CAPITAL RAISE’ TRADING HALT**
- * **TELIX PROMOTES US OPERATIONS HEAD DR DARREN PATTI TO COO**
- * **TIM CHAPMAN REPLACES HERAMED DIRECTOR DORON BIRGER**
- * **BIO-MELBOURNE 5th MEDTECH SEMINAR POSTPONED TO APRIL**

MARKET REPORT

The Australian stock market was up 0.11 percent on Tuesday March 12, 2024, with the ASX200 up 8.3 points to 7,712.5 points. Twenty-five of the Biotech Daily Top 40 stocks were up, 11 fell and four traded unchanged.

Mesoblast was the best, up 7.5 cents or 23.4 percent to 39.5 cents, with 36.6 million shares traded. Resonance rose 11.5 percent; Imugene increased 9.5 percent; Prescient rose eight percent; Universal Biosensors was up 7.1 percent; Dimerix and Neuren were up five percent or more; Starpharma improved four percent; Actinogen, Opthea, Orthocell, Polynovo and SDI were up more than three percent; Paradigm and Resmed rose more than two percent; Compumedics, Cyclopharm, Nanosonics, Next Science, Percheron (Antisense) and Proteomics were up more than one percent; with Clarity, Clinuvvel, CSL, Medical Developments, Pro Medicus and Volpara up by less than one percent.

Cynata led the falls, down one cent or 5.3 percent to 18 cents, with 478,121 shares traded; followed by Immutep down five percent to 38 cents with one million shares traded. Impedimed fell 4.35 percent; Atomo lost 3.45 percent; 4D Medical, Alcidion, Amplia and Nova Eye shed two percent or more; Avita was down 1.8 percent; with Cochlear, Genetic Signatures and Telix down by less than one percent.

DIMERIX

Dimerix says it has “commitments” for a \$20 million placement at 30 cents a share to complete its phase III trial of DMX-200 for focal segmental glomerulo-sclerosis (FSGS). Yesterday, Dimerix said that an interim analysis of 72 patients in its up-to 286-patient, phase III focal segmental glomerulosclerosis (FSGS) trial showed DMX-200 reduced proteinuria more than placebo (BD: Mar 11, 2024).

Today, the company said the placement price was a 29.2 percent premium to the 30-day volume weighted average price of 23.2 cents and a 14.5 percent premium to the five-day volume weighted average price of 26.2 cents.

Dimerix said the funds would be used to prepare and submit the appropriate regulatory applications as well as partnering activities, and that it would focus on the execution of potential licensing deals for available jurisdictions, including in the US and China.

The company said Euroz Hartleys was sole lead manager for the capital raise.

Dimerix was up 1.5 cents or five percent to 31.5 cents with 41.5 million shares traded.

BLEUECHIIP

Bluechiip says its five-for-seven rights offer at 0.7 cents a share has raised \$1,302,609 of a hoped-for \$4,000,000, taking the total raised with the placement to \$2,130,000.

Last month, Bluechiip said it raised \$840,000 in a placement and hoped to raise up-to \$4 million in a pro-rata, a non-renounceable offer at 0.7 cents, a 43.1 percent discount to the five-day volume weighted average price of 1.23 cents (BD: Feb 5, 2024).

Today, the company said it reserved the right to issue the shortfall within three months of the closing date.

Bluechiip said the funds would be used for North American sales and marketing activities and for general corporate and working capital purposes.

Bluechiip was unchanged at 0.7 cents.

SNOW MEDICAL RESEARCH FOUNDATION

UNIVERSITY OF QUEENSLAND, AUSTRALIAN NATIONAL UNIVERSITY

Snow Medical Research says it will provide \$8 million fellowships each to Australian National University’s Prof Lara Malins and University of Queensland Prof Loic Yengo.

Snow Medical said that the fellowships were provided over eight years as part of the Foundation’s funding of the Australian bio-medical research sector.

The Foundation said Prof Malins was researching chemical biology and peptide synthesis, “to unlock new pathways in drug discovery and development”.

Snow said Prof Yengo had expertise in statistical genomics and human genetics to understand how genetic variations influenced health for disease prevention and treatment. The University of Queensland said Prof Yengo would use the funds to analyze DNA sequences from millions of participants, to increase participation of people with diverse ancestries; and the genetic research could allow doctors “to accurately predict whether a patient is at risk of developing common diseases, decades before any symptoms would become evident”.

Prof Yengo said the Snow Fellowship was “an extraordinary opportunity to do this work at the necessary scale, and this will include a 10-fold increase in the representation of people with non-European ancestries in genetic health data around the world.”

Snow Medical chair Tom Snow said the fellowships aimed “to create an environment where diversity, inclusivity and gender equality are not just valued but seen as essential components of exceptional research and high-performing teams”.

ANTERIS TECHNOLOGIES

Anteris says it has 30-day data on all 28 patients in its first-in-human study and all 15 patients in its US early feasibility study for its Duravr transcatheter heart valve.

Last year, the company said 30-day results from its seven-patient third cohort showed “excellent hemodynamic performance” with effective orifice areas of 2.04 cm^2 at 30 days and a mean pressure gradient decrease of 87 percent (BD: Jun 13, 2023).

Today, Anteris said 30-day results from all 28 patients in its first-in-human study showed an effective orifice area of 2.13 cm^2 , a mean pressure gradient of 7.9 mm/Hg and a Doppler velocity index of 0.57.

Anteris said 30-day results of 15 patients showed an effective orifice area of 2.2 cm^2 , a mean pressure gradient of 7.5 mm/Hg and a Doppler velocity index of 0.64.

The company said that higher effective orifice areas and lower mean pressure gradient decreased the amount the heart had to work while a higher Doppler velocity index indicated improved blood flow.

Anteris was up 80 cents or 4.2 percent to \$20.00.

ARTRYA

Artrya says it will conduct a non-clinical validation test of its Salix coronary Anatomy software with the Carrollton, Georgia-based hospital group Tanner Health System.

Artrya said Tanner Health was “a five-hospital, non-profit health system providing ... personalized health care to communities across West Georgia and East Alabama”.

The company said it would “non-clinically validate and test Salix coronary anatomy” software in the Tanner Health System’s workflow while the product was going through the US Food and Drug Administration 510(k) clearance process; and develop and expand the specific use cases for its software at Tanner Health premises.

The company said it would pay Tanner Health 500,000 performance options by August 30, 2024 subject to completion of test integration and 680,000 options in four instalments over five years following integration, subject to conditions; all exercisable at the five-day volume weighted average price at the time of issue within five years of issue.

Artrya was up one cent or 3.7 percent to 28 cents.

RECCE PHARMACEUTICALS

Recce says it has begun the 20-minute cohort in its phase I/II fast infusion trial of 3,000mg R327 for urinary tract infection, having tested 15, 30, 45 and 60-minutes.

Last year, Recce said an independent safety committee had unanimously approved a faster R327 infusion rate of 3,000mg administered in 15 minutes in its phase I/II trial for urinary tract infections and urosepsis; and later, said it had dosed the first male and female subjects at the faster infusion rate (BD: Oct 24, Nov 7, 2023).

Today, the company it had established that the dose of 3,000mg, administered at varying infusion times between 15 minutes and one hour, was safe and that achieving multiple infusion time stamps was in line with intended regulatory submissions.

Recce said the remaining participants would be dosed in “the coming days”.

Recce chief executive officer James Graham said the company was pleased to continue advancements within and surrounding our R327 clinical trials”.

“The additional infusion time at 3,000mg over 20 minutes highlights a compelling safety profile with the potential to treat the millions of patients worldwide that suffer from [urinary tract infection and, or urosepsis] each year,” Mr Graham said.

Recce fell 1.5 cents or 3.5 percent to 41.5 cents.

MELODIOL GLOBAL HEALTH

Melodiol has told the ASX that it considers its financial condition sufficient to warrant it as an ongoing concern, and that it has a track record of raising capital when required.

The ASX said the company's Appendix 4C for the three months to December 31, 2023, it reported negative net operating cash flows of \$2,206,000, cash of \$692,000, unused finance facilities of \$111,000 and an estimated 0.36 quarters cash for the three months to December 2023.

The ASX noted that in its response to section 8.6 of its financial report Melodiol said it expected a "downwards trend in its operating outflows" to continue and that it had "consistently demonstrated that it has various avenues by which it can draw down further capital, and a track record of utilizing these various avenues when required".

The ASX said in light of the information contained in its financial reports, did Melodiol consider its financial condition was sufficient to warrant its continued listing on as required under Listing Rule 12.2?

Melodiol replied that Listing Rule 12.2 did not "set out specific metrics that must be met to form the ASX's view on a company's financial condition ... [but] nevertheless, considers its financial condition is sufficient to warrant continued quotation of its securities and its continued listing on ASX under Listing Rule 12.2".

"This is demonstrated by its track record of ongoing improvement in operating cash outflows and its historical track record to raise additional capital as and when required," the company said.

Melodiol said its Appendix 4C responses were "responses to template questions which do not allow for in-depth responses ... [and] demonstrate that [the company's] financial condition is sufficient to warrant continued quotation of its securities ... when considered in conjunction with the significant trend of operating cash outflow improvement that has been historically demonstrated".

The company said it had "a strong track record of raising capital ... [and] since June 2020 ... has raised more than \$48 million in debt and equity capital, 22 times the quarterly outflow provided in the Appendix 4C, not counting for any improvements in cash flows in 2023-'24".

Melodiol fell 0.05 cents or 8.3 percent to 0.55 cents with 6.2 million shares traded.

VOLPARA HEALTH TECHNOLOGIES

Visioneering says the New Zealand High Court has ordered a share-holders scheme meeting to vote on Lunit Inc's acquisition of the company.

Last year, Volpara said the Seoul, South Korea-based Lunit Inc would acquire the company for \$1.15 a share, valuing it at \$295.7 million, through a scheme implementation agreement (BD: Dec 14, 2023).

Today, the company said the meeting will be held online and in person on April 12, 2024 at 11am (AEST), with details to follow.

Volpara was up half a cent or 0.45 percent \$1.125.

PAINCHEK

Painchek has requested a trading halt "pending an announcement regarding a capital raise".

Trading will resume on March 14, 2024, or on an earlier announcement.

Painchek last traded at 2.9 cents.

TELIX PHARMACEUTICALS

Telix says it has promoted US head of operations and general manager Dr Darren Patti as chief operating officer, effective from March 11, 2024.

Telix said Dr Patti had been its head of US operations since March 2021 and general manager for the Americas, and prior to joining the company had been head of operations for Sofie Biosciences.

According to his LinkedIn profile, the Naperville, Illinois-based Dr Patti holds a Bachelor of Arts from Carbondale's Southern Illinois University and a Doctor of Pharmacy from Chicago's University of Illinois.

Telix fell six cents or 0.5 percent to \$11.23 with 747,039 shares traded.

HERAMED

Heramed says advisor Tim Chapman will replace non-executive director Doron Birger on an interim basis, effective immediately.

Heramed said Mr Chapman had been supporting the company in an advisory capacity as it transitioned from research and development hardware to a software-as-a-service business, but did not state Mr Chapman's previous places of work, nor his qualifications. The company said Mr Chapman's appointment was on an interim basis as it was "currently engaged in discussions with several candidates that will help support the commercialization of Heracare in its next phase".

Heramed said the appointment was "a precursor to a number of structural changes the business is intending to implement in the coming weeks".

Heramed was up 0.1 cents or 5.3 percent to two cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says its fifth medical technologies seminar on innovations in cardiovascular health has been rescheduled to April 16, 2024.

Last year, the Bio-Melbourne Network said its medical technology seminar 'Innovations in Cardiovascular Health: Bridging Technology and Care' would be held on February 13, 2024 (BD: Dec 20, 2023).

Today, the Network said those who had registered to attend the event on February 13, would have their ticket automatically transferred to the delayed date.

The Bio-Melbourne Network said the event would be held at the Science Gallery Melbourne Theatre, 114 Grattan Street, Carlton on April 16, 2024 from 7.45am to 10.30am (AEST), with details and registration at: <https://bit.ly/3NA1I9S>.