Biotech Daily

Thursday June 20, 2024

Daily news on ASX-listed biotechnology companies

*** ASX EVEN, BIOTECH DOWN: DIMERIX UP 10%; CYNATA DOWN 14%**

*** RADIOPHARM 'UP TO $18m LANTHEUS PLACEMENT, ASSET SALE'**

*** BOTANIX: FDA APPROVES SOFDRA FOR UNDERARM SWEATING**

*** CONTROL BIONICS: 'TGA APPROVES DROVE WHEELCHAIR MODULE'**

*** ANTERIS 'COMASUR BALLOON IMPLANTS DURAVR IN 13-PATIENTS'**

*** IMRICOR CONDUCTS 1st ATRIAL FLUTTER ABLATION**

*** RACE APPOINTS GEORGE CLINICAL FOR RC220 SOLID TUMOR TRIAL**

*** TRIVARX ENROLS 91% OF HEART RHYTHM-DEPRESSION TRIAL**

*** ALLEGRA: DR NICHOLAS HARTNELL FILES BIDDER'S STATEMENT**

*** EMYRIA, TRANSCEND AT EMPAX FOR METHYLONE PTSD TRIAL**

*** ONE FUNDS, SAVILLE TAKES 19% OF BLUECHIIP**

MARKET REPORT

The Australian stock market was even on Thursday June 20, 2024, with the ASX200 slipping just 0.3 points to 7,769.4 points. Sixteen of the Biotech Daily Top 40 were up, 20 were down, three traded unchanged and one was untraded. All three Big Caps fell.

Dimerix was the best, up 5.5 cents or 9.9 percent to 61 cents, with 4.4 million shares traded. Actinogen and Next Science climbed more than six percent; Imugene improved 5.4 percent; Emvision, Impedimed and Paradigm were up more than four percent; Alcidion, Percheron and Prescient rose more than two percent; Cyclopharm, Genetic Signatures, Medadvisor, Medical Developments and Telix were up one percent or more; with Pro Medicus up by 0.4 percent.

Cynata led the falls for the second day in a row, down four cents or 14.3 percent to 24 cents, with 620,621 shares traded. 4D Medical, Clarity and Curvebeam lost more than seven percent; Micro-X was down 6.7 percent; Cochlear fell 4.8 percent; Proteomics and Syntara were down more than three percent; Avita, Mesoblast, Opthea and SDI shed more than two percent; Amplia, Clinuvel, Immutep, Orthocell, Resonance and Starpharma were down more than one percent; with CSL, Nanosonics, Neuren, Polynovo and Resmed down by less than one percent.

RADIOPHARM THERANOSTICS

Radiopharm says it has raised $7.5 million at 5.0 cents a share in a placement to Lantheus Holdings and $3 million for selling two pre-clinical assets to Lantheus.
Radiopharm said the North Billerica, Massachusetts-based radio-pharmaceutical company Lantheus had an option to invest a further $7.5 million within six-months through unlisted options, exercisable at 5.0 cents each within six months of issue.
The company said Lantheus would receive one option for every four shares acquired, exercisable at six cents each by August 2026, subject to shareholder approval.
Radiopharm said in a separate agreement it had assigned and sub-licenced its TROP2 targeting nanobody and LRRC15 targeting monoclonal antibody pre-clinical assets to Lantheus for $3.0 million.
The company said the funds would be used for “drug manufacturing, clinical trials and general working capital”.
Radiopharm said Riley Securities was its financial advisor.
The company said that the licence agreement contained “typical assignee protections such as risk allocation clauses and representations and warranties made by the company … in respect of each entity’s standing and its ownership of and rights in the assets being assigned and sold”.
Separately, Radiopharm requested a trading halt pending an announcement “in relation to a potential capital raising”.
Trading will resume on June 24, 2024, or on an earlier announcement.
Radiopharm last traded at 3.4 cents.

BOTANIX PHARMACEUTICALS

Botanix says the US Food and Drug Administration has approved Sofdra for excessive underarm sweating in adults and children aged nine years and older.
Earlier this year, Botanix said the US Food and Drug Administration (FDA) had accepted a resubmission for sofpironium bromide gel, or Sofdra, for excessive underarm sweating, follow revisions to its instruction leaflet (BD: Jan 22, 2024).
Today, the company said the FDA had approved Sofdra as a treatment of primary axillary hyperhidrosis, or excessive underarm sweating, in adults and children nine years of age and older.
Botanix said the approval was supported by results from two phase III studies of Sofdra in 701 patients which met primary and secondary endpoints including “statistically meaningful changes from baseline” in gravimetric sweat production and a hyperhidrosis disease severity.
Botanix said there were about 10 million people in the US with primary axillary hyperhidrosis, and that Sofdra was the “first and only new chemical entity” approved by the FDA as a treatment.
The company said it planned to launch a “patient experience program” by October 2024, to give qualified patients early access to Sofdra, with a “broader launch” and first revenue from sales expected this year.
Botanix chief executive officer Dr Howie McKibbon said approval was “a transformative event for Botanix as we transition from a development stage to a revenue generating dermatology company”.
The company said it would remain in a trading halt pending an announcement regarding a capital raising.
Trading is expected to resume on June 21, 2024, or on an earlier announcement.
Botanix was in a trading halt and last traded at 33.5 cents.

CONTROL BIONICS

Control Bionics says the Australian Therapeutics Good Administration has approved its Drove autonomous wheelchair module as a class one medical device.

Last year, Control Bionics said it launched “the world’s first autonomous driving wheelchair module” using its Neuronode thought-to-computer technology (BD: Apr 19, 2023).

At that time, the company said the Drove module could be retro-fitted to powered wheelchairs, allowing users “to move their chair autonomously and precisely without a joystick, to specific locations within the home - a world first”.

Today, Control Bionics said the device had been included on the Australian Register of Therapeutic Goods following about a year of internal and external testing.

The company said the approval allowed it to sell the device in Australia, with an official launch to take place “in the coming weeks”.

Control Bionics said Drove was designed and manufactured in Australia and integrated “seamlessly with existing wheelchair systems, enabling users to navigate their environment autonomously and safely”.

Control Bionics chief executive officer Jeremy Steele said approval was “a fantastic confirmation of the quality of our Drove solution”.

“I am delighted for our team who have worked for years to design, test and get this device registered,” Mr Steele said.

“I am even more excited to be able to provide independence to Australians currently living with conditions that impact their ability to control their own wheelchair,” Mr Steele said.

“Work is also progressing well on a similar approval in the US with the [Food and Drug Administration], supported by a grant from the [Amyotrophic Lateral Sclerosis (ALS)] Association received earlier this year,” Mr Steele said.

“We are encouraged by the revenue growth opportunity Drove provides Control Bionics,” Mr Steele said.

Control Bionics rose 1.4 cents or 32.6 percent to 5.7 cents with 20.2 million shares traded.

ANTERIS TECHNOLOGIES

Anteris says a 13-patient cohort shows its balloon-expandable Comasur delivery system successfully implanted its Duravr aortic replacement valve.

Anteris said the Comasur delivery system was designed to “provide controlled deployment and accurate placement of the Duravr [transcatheter heart valve (THV)] with balloon-expandable delivery, allowing precise alignment with the heart’s native commissures to achieve optimal valve positioning”.

The company said the final cohort of patients confirmed the performance of Comasur prior to a phase III registration study, with the 30-day data of the 13-patient cohort showing Duravr implanted using the Comasur led to an effective orifice area of 2.25 sq.cm compared to 1.58 sq.cm for standard-of-care and mean pressure gradient of 7.81mm/Hg compared to 11.94mm/Hg for standard-of-care.

The company said the results showed “improved [blood flow] performance relative to earlier favorable clinical results” from cohorts one-to-four of the first-in-human study of Duravr (BD: Jul 11, 2022, Jan 22, May 31, Jun 13, Jul 31, 2023, Mar 12, 2024).

Anteris managing-director Wayne Paterson said the Duravr transcatheter heart valve and Comasur delivery system were designed “to deliver a highly differentiated, new class of valve which can be easily deployed via a balloon expandable platform”.

“This latest data confirms the Duravr … system can deliver market leading haemodynamic performance in an intuitive, easy to use, balloon expandable platform,” Mr Paterson said.

Anteris fell 30 cents or 1.6 percent to $18.70.

IMRICOR MEDICAL SYSTEMS

Imricor says the Dubrava University Hospital has performed its first interventional cardiac magnetic resonance (ICMR)-guided atrial flutter ablation with its products.
Imricor said additional procedures were being scheduled “on a regular basis” at the Dubrava, Croatia-based hospital, as it meets increasing demand for ablations.
Imricor managing-director Steve Wedan said Dubrava was “a very busy site with high volume and a limited number of conventional electro-physiology labs”.
“They are relying on performing ICMR procedures with our products to effectively add a new [electro-physiology] lab to their practice,” Mr Wedan said.
“The hospital is targeting significantly more total ablation procedures this year compared to last year, and physicians are planning to ramp up atrial flutter ablations in the ICMR lab to help meet that demand,” Mr Wedan said.
Imricor was unchanged at 41.5 cents.

RACE ONCOLOGY

Race says George Clinical International will be the contract research organization for its 34-patient, phase Ia/Ib trial of RC220 bisantrene in solid tumor patients.
Race said the phase I, open-label trial would be conducted in Australia, Hong Kong and South Korea, with the phase Ia stage to study ascending doses of RC220 bisantrene for safety, tolerability, pharmacokinetics, n6-methyladenosine RNA effects and the maximum tolerated dose alone and with the anthracycline chemotherapy doxorubicin.
The company said the phase Ib stage would assess the optimal dose of RC220 bisantrene with doxorubicin for safety, tolerability, preliminary cardioprotective and anticancer efficacy signals and its cardiotoxicity compared to doxorubicin.
Race said it estimated the trial would recruitment about 34 patients in 2026 and test RC220 bisantrene in a range of cancer types.
The company said it would pay Sydney’s George Clinical $1,071,067, with additional payments following the completion of milestones.
Race said it expected the total cost to be about $6 million, based on the 34-patient target, but would be “dependent on the number of recruited patients and other variables of trial execution”, with additional costs for drug supply and analysis.
Race chief executive officer Dr Daniel Tillett said the agreement was “a significant milestone” to bring RC220 bisantrene to the clinic to potentially protect patients from the heart damage caused by anthracyclines while improving cancer treatment.
Race fell 15.5 cents or 7.7 percent to $1.865.

TRIVARX (FORMERLY MEDIBIO)

Trivarx says it has enrolled 362 patients of a hoped-for 400 patients in the study of its MEB-001 sleep signal algorithm for major depressive episodes.
Last year, the-then Medibio said it had begun a trial of its MEB-001 “sleep signal analysis” algorithm for major depressive episodes at 14 US sleep centres (BD: Sep 4, 2023).
Today, the company said it expected to complete the trial and have results “in the coming weeks”, which would be used for US Food and Drug Administration approval of MEB-001.
Trivarx said it had appointed the Milwaukee, Wisconsin-based Dr Drew Palin as a strategic advisor to “assist the company in advancing a number of commercial opportunities including additional partnership agreements, licencing opportunities and commercialization initiatives”.
Trivarx was unchanged at 2.5 cents.

ALLEGRA MEDICAL TECHNOLOGIES

Allegra says director Dr Nicholas Hartnell has filed his bidder's statement on behalf of himself, Robinwood and Allegra Innovations Pty Ltd.
In May, Allegra said Allegra Innovations would pay 0.4 cents a share in a cash take-over bid, valuing it at $478,444 (BD: May 27, 2024).
Today, the company said the independent directors "unanimously recommended" that shareholders accept the offer.
Allegra was in a suspension and last traded at 2.9 cents.

EMYRIA

Emyria says the New York-based Transcend Therapeutics will use its Empax Centre to evaluate the safety and efficacy of methylone for post-traumatic stress disorder.
In April, Emyria said it had opened the Empax Centre with Perth's Pax Centre for the delivery and evaluation of 3,4 methylene-dioxy-meth-amphetamine (MDMA)-assisted therapy (BD: Apr 10, 2024).
Today, the company said the trial planned to enrol up-to 79 patients and would study the effects of methylone, a novel 3,4-methlene-dioxy-meth-amphetamine (MDMA) analogue, on neuroplasticity and post-traumatic stress disorder (PTSD) symptoms.
Emyria said there were "no material conditions precedent under the agreement" but that if the trial proceeds as planned it expected to recruit at least 20 participants and provide comprehensive specialist mental health services.
The company said the mental health services included "initial screenings, ongoing safety and efficacy assessments, precise dosing, patient monitoring and data entry, tasks that require the expertise of trained psychiatrists and therapists".
Emyria said the service fees would be structured to align with market rates, which it currently bulled at between $150 and $600 per hour, with each trial participant requiring about 30-to-50 hours of service for the study.
Emyria was unchanged at 4.6 cents.

BLUECHIIP

One Funds Management Ltd says it has increased its substantial shareholding in Bluechiip from 96,000,000 shares (14.06%) to 221,818,181 shares (18.77%).
The Sydney-based One Funds said as trustee for the Saville Capital Emerging Companies Fund it bought shares between May 12, 2023 and June 13, 2024, with the single largest purchase 56,818,181 shares for $250,000, or 0.44 cents a share.
Earlier this year, Bluechiip it had raised $1,302,609 of a hoped-for $4,000,000 in a five-for-seven entitlement offer at 0.7 cents a share, taking the total raised with a previous placement to $2,130,000 (BD: Mar 12, 2024).
Bluechiip was up 0.1 cents or 25 percent to 0.5 cents with 2.4 million shares traded.