Biotech Daily

Tuesday June 18, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: CYNATA UP 17%; DIMERIX DOWN 7%**

*** MICRO-X TO TRIAL MOBILE STROKE CT; 2nd AIRPORT SCANNER BY 2025**

*** FEDERAL $15m FOR WEHI TERNARX 'CANCER PROTEIN DEGRADER'**

*** CLINUVEL: AFAMELANOTIDE FOR FAIR-SKINNED PARKINSON'S PATIENTS**

*** CARDIEX EXPECTS SALES UP 100% TO $12m**

*** RECCE R327 ADDED TO W.H.O. REPORT**

*** RACE: US RARE PAEDIATRIC DISEASE STATUS FOR I.V. RC220**

*** ANTERIS: 'FDA SUPPORTS DURAVR STUDY DESIGN'**

*** UNIVERSAL BIOSENSORS RECEIVES $3.8m FEDERAL R&D TAX INCENTIVE**

*** GENETIC TECHNOLOGIES GENE BY GENE STARTS US GENETYPE TESTING**

*** PERENNIAL TAKES 16% OF GENETIC SIGNATURES**

*** REGAL FUNDS TAKES 6.75% OF GENETIC SIGNATURES**

*** INSIGNIA TAKES 9% OF IMMUTEP**

*** INVEX LOSES DIRECTOR DR MEGAN BALDWIN**

MARKET REPORT

The Australian stock market was up 1.01 percent on Tuesday June 18, 2024, with the ASX200 up 77.8 points to 7,778.1 points. Sixteen of the Biotech Daily Top 40 were up, 13 were down and 11 traded unchanged.

Cynata was the best, up 4.5 cents or 17.3 percent to 30.5 cents, with 150,789 shares traded; followed by Proteomics, up 13 cents or 16.05 percent to 94 cents. Genetic Signatures climbed 5.2 percent; Alcidion and Mesoblast were up more than four percent; Polynovo improved 3.4 percent; 4D Medical, Clinuvel, Emvision, Medadvisor and Prescient rose more than two percent; Cochlear, CSL and Orthocell were up more than one percent; with Clarity, Nanosonics, Neuren and Pro Medicus up by less than one percent.

Dimerix led the falls, down 4.5 cents or 7.3 percent to 57 cents, with 9.1 million shares traded. Atomo, Immutep and Universal Biosensors shed six percent or more; Nova Eye and Percheron fell more than four percent; Imugene and Next Science were down more than three percent; Avita and Starpharma shed more than two percent; Impedimed and Resonance were down more than one percent; with Resmed and SDI down by less than one percent.

MICRO-X

By JAMIE MILLER, DEPUTY EDITOR

Micro-X says it expects to trial its computed tomography (CT) imaging device for stroke and to send a second airport baggage security scanner prototype for testing before 2025.

At an investor display at Melbourne's Monash University Caulfield campus, Micro-X chief executive officer Kingsley Hall said the company had "three really significant global projects" but that its Rover portable chest x-ray device for hospital use would continue to be the company's main revenue generating product.

Mr Hall said although the company had "disrupted the market with a fantastic piece of kit, [the Rover], it was a small company from Adelaide" and was looking for sales partners and distributors to get its Rover portable x-ray technology "into the market sooner and with greater impact".

Mr Hall said that, to date, the company had sold about 380 units of the Rover in various jurisdictions, but it needed partners to sell to the "larger end of town" and compete with standard x-ray providers, including Siemens and Canon.

At the event, the company displayed its three development projects, including its portable CT stroke diagnostic, its portable Argus scanner for military applications including bomb detection and its airport security full-body scanner and baggage scanner.

Micro-X chief operating officer Anthony Skeats said the company was developing a computed tomography (CT) device for imaging and diagnosing ischaemic or haemorrhagic strokes in an ambulance.

Mr Skeats said the device used the company's patented nanotube technology and could be fitted to make existing ambulances "stroke capable" reducing the need for specialized mobile stroke unit ambulances.

Mr Skeats said Micro-X expected a stroke-capable ambulance would cost "about a third" of the operating cost of a specialized mobile stroke unit ambulance, which was about $1 million a year.

Micro-X said it was planning to conduct trials at the Royal Melbourne Hospital by August, imaging about five groups of 27 stroke patients, compared with standard-of-care.

Mr Skeats said the company had planned to expand the trial to the Royal Adelaide Hospital and Melbourne's Box Hill Hospital.

Mr Skeats said, once completed, Micro-X would conduct a field test of the device with the South Australian Ambulance Service, but that further funding was required.

In March, Micro-X said it had its first commercial Argus x-ray order from an undisclosed "Middle Eastern" company (BD: Mar 21, 2024).

Today, the company said Argus was being commercialized, with sales expected "soon".

Micro-X chief scientific officer and US chief executive officer Dr Brian Gonzales said the company's airport security scanner and baggage scanner used the Argus technology and it expected to send a second prototype baggage scanner to the US before 2025.

In 2021, the company said it had US Government contracts worth up to $US4.1 million for its baggage screening scanner and self-screening portal (BD: Sep 29, 2021).

Last year, Micro-X said the US Department of Homeland Security's Transportation Security Administration (TSA) had extended its $7.25 million, 18- month baggage scanner contract with a further $21 million over 40-months (BD: Jul 24, 2023).

Today, Mr Gonzales said the company was manufacturing a second prototype baggage scanner to send to the Transportation Security Administration for testing, with the walk-in body scanner still in development.

"The goal is to have a set of six scanners in an airport in the US in about a year and a half from now," Mr Gonzales said.

Micro-X was unchanged at nine cents.

FEDERAL GOVERNMENT, TERNARX
WALTER AND ELIZA HALL MEDICAL RESEARCH INSTITUTE

The Walter and Eliza Hall Institute says it has launched a spin-out company, Ternarx, to develop “targeted protein degrader technology” as a cancer treatment.

WEHI said the Minister for Health and Aged Care Mark Butler announced the launch of Ternarx at the company’s laboratory facilities at its Bundoora campus.

According to the WEHI website, Ternarx was a biotechnology company “focused on developing a pipeline of targeted protein degrader therapies, as well as platform technology and capability in this cutting-edge, new approach to drug development”.

The Institute’s website said Ternarx had a facility in Melbourne and was a spin-out company funded through a $15 million grant from the Australian Government’s Medical Research Future Fund, Frontier Health and Medical Research initiative and was part of a collaboration with the Children’s Cancer Institute and Melbourne’s Monash University.

The website said Ternarx’s chief executive officer was former Oncology One chief executive officer Dr Joanne Boag, its chief operating officer was Dianna McKiernan and its directors included Amplia chief executive officer Dr Chris Burns, Dr Amanda Reese and WEHI’s Dr Victoria Jameson.

A media release from the Federal Minister for Health and Aged Care Mark Butler said that in 2023, the Federal Government awarded $15 million to establish the Australian Centre for Targeted Therapeutics, a collaboration between the Walter and Eliza Hall Institute, the Children’s Cancer Institute and Melbourne’s Monash University.

The Federal Government said that WEHI had “spun-out Ternarx to form a globally competitive biotechnology company and commercialize targeted protein degrader medicines and technology”.

The media release said that targeted protein degrader technology was designed to destroy the proteins that underpin cancers.

“Many types of cancer can be traced to proteins, but the majority of these do not respond to drug treatment,” the media release said and Ternarx would develop “new protein degrader technology to create next-generation cancer medicines with greater efficacy and fewer side effects”.

“Unlike conventional drugs that only inhibit the activity of proteins, targeted protein degraders can target and destroy disease-causing proteins, completely removing the proteins from the cancer,” the Federal Government said.

The Government said that, initially, Ternarx would focus on neuroblastoma and prostate cancer and if successful, the technology could be expanded to other types of cancer and disease-causing proteins, like those associated with currently untreatable inflammatory diseases like ulcerative colitis and Crohn’s disease, and neurological conditions such as Alzheimer’s disease, Huntington’s disease and Parkinson’s disease.

“It is an honor to officially launch Ternarx, a significant and exciting addition to Australia’s growing, high-quality medical and biotech sector,” Mr Butler said.

“The technology it is pursuing has huge potential to create the next generation of treatments for cancer and other diseases,” Mr Butler said.

“Prostate cancer is the most commonly diagnosed cancer in men and neuroblastoma tragically claims the lives of more children under five [years of age] than any other cancer,” Mr Butler said.

“Protein degrader technology promises cancer treatments that are more effective, with fewer side effects,” Mr Butler said.

“With support from the MRFF, our brilliant researchers can turn their ideas into new treatments that have potential to save thousands of lives, not just here but around the world,” Mr Butler said.

CLINUVEL

Clinuvel says that following pre-clinical work it will evaluate afamelanotide as a melanocortin-1 receptor MC1R) therapy in six fair-skinned Parkinson's patients.
Clinuvel said the program would aim to determine whether afamelanotide, through melanocortin-1 receptor activation, was able to lower the alpha-synuclein toxin in blood levels in Parkinson's disease patients and positively affect neurons of the midbrain.
The company said that large studies had shown that fair-skinned patients had a higher risk of Parkinson's disease associated with a malfunctioning MC1R; and since afamelanotide was "known to optimize the function of the MC1R, it is hypothesized that the drug treatment would have a positive effect in [Parkinson's disease] by lowering alpha-synuclein, as recently demonstrated in preclinical studies".
Clinuvel said that the CUV901 study was "the first human study evaluating the effect of afamelanotide in [Parkinson's disease] as a therapeutic option".
The company said that the first objectives of the open-label study were the safety of afamelanotide, while determining alpha-synuclein in blood and assessing visual changes in the midbrain, with secondary endpoints to assess cognitive functions.
Clinuvel said that patients aged between 40 and 85 years old would receive 11 doses of 0.08mg/kg afamelanotide on each day of drug administration, over 56 days, with the first patients expected to enrol before the end of 2024.
Clinuvel chief scientific officer Dr Dennis Wright said the company was "immensely pleased to initiate a highly innovative study for afamelanotide".
"At the heart of the problem in Parkinson's lies the loss of dopamine producing neurons in the brain due to toxicity caused by alpha-synuclein," Dr Wright said. "There is now evidence that afamelanotide, by binding to MC1R, could maintain stability and integrity of the affected neurons and slow down progression of the disorder."
"By analyzing blood and brain scans of the substantia nigra, we will learn of afamelanotide's potential effect in Parkinson's," Dr Wright said.
Clinuvel was up 42 cents or 2.9 percent to $15.02 with 124,394 shares traded.

CARDIEX

Cardiex chief executive officer Craig Cooper says sales for the year to June 30, 2024 are expected to be up 100 percent to more than $12 million compared to the prior year.
"As I noted in our last quarterly [report], we're on track for record revenues for 2023-'24 with strong performance from our pharma sales group, as well as in our traditional sales to the research and clinician markets," Mr Cooper said.
Mr Cooper said that sales in May of the company's central blood pressure monitoring systems "were the highest for the previous six-month period, and with June traditionally being our strongest sales month in this sector, we are confident of achieving a record year of research sales by financial year-end".
Mr Cooper said that initial production units of the Conneqt Pulse were scheduled to arrive the first week of July.
Mr Cooper said the company had relaunched its Conneqt Health website, which had a waitlist for those wanting access to the Pulse and it was expected that the company would have more than 20,000 people on the waitlist by the time of taking orders for the Pulse.
Mr Cooper said the company had signed its first physician partnership for the Pulse with Physioage, a network of clinicians specializing in naturopathic, functional, and longevity medicine; and had a partnership with Heartbeat Health, the largest decentralized cardiology practice in the US.
Cardiex was up 0.9 cents or 15.5 percent to 6.7 cents with 1.0 million shares traded.

RECCE PHARMACEUTICALS

Recce says its R327 has been added to the World Health Organization's report of Antibacterial Agents in Clinical Development and Preclinical Development.

Recce said that inclusion of the R327 anti-infective candidate in the report meant it was "uniquely classified as an adenosine triphosphate (ATP) production disruptor, the only compound under this category … [and] recognized as a novel treatment for a broad range of life-threatening and resistant bacteria".

The company said that the report covered "traditional and non-traditional antibacterial agents in development worldwide and evaluates to what extent the present pipeline addresses infections caused by priority pathogens, according to the updated 2024 WHO bacterial priority pathogens list".

Recce said that R327 had been defined by the World Health Organization as an adenosine triphosphate production disruptor and was the only compound in this category.

The company said that adenosine triphosphate was the source of energy for use and storage at the cellular level and disruption of adenosine triphosphate production in bacterial cells when targeted as the main mechanism of action, not secondary to other cell perturbation mechanisms, carried the potential to confer activity against both Gram-positive and Gram-negative pathogens.

Recce chief executive officer James Graham said the company was "pleased that R327 has been included in the list of antibacterial products aimed at tackling the urgent global health threat posed by antibiotic resistance".

"There is a demand for new antibiotic therapies, and this report further showcases R327's potential as a novel treatment for a broad range of life-threatening and resistant bacteria," Mr Graham said.

Recce was up four cents or 7.3 percent to 59 cents.

RACE ONCOLOGY

Race says the US Food and Drug Administration has extended rare paediatric disease status to RC220 bisantrene for paediatric acute myeloid leukaemia (AML).

In 2018, Race said the FDA has granted Bisantrene rare paediatric disease designation (RPDD) for paediatric acute myeloid leukaemia (BD: Jul 18, 2018).

Today, the company said the designation had been extended to the RC220 intra-venous formulation of bisantrene.

Race said that the designation was granted "for new treatments of serious or life-threatening diseases which affect fewer than 200,000 people in the US and which primarily affect individuals less than 18 years of age [and] qualifies a sponsor eligible to receive a priority review voucher (PRV) from the US FDA at the time of marketing approval or authorization".

The company said that the reported purchase prices of PRVs to third parties on the open market have averaged more than $US100 million.

Race chief executive officer Dr Daniel Tillett said the designation was "incredibly valuable as not only does it offer eligibility for the award of a PRV, but the ability to work with passionate clinicians and regulators to bring help to children and adolescents facing an enormously challenging disease with few effective treatment options".

Race said it planned to submit a US investigational new drug application for RC220 bisantrene in 2025.

Race was up 26 cents or 14.9 percent to $2.01 with 696,290 shares traded

ANTERIS TECHNOLOGIES

Anteris says the US Food and Drug Administration “has indicated support for key study design aspects” for its Duravr THV biomimetic aortic replacement valve.

Anteris said it had a pre-submission meeting with the FDA to confirm the structure of the study, included sites outside the US, randomization of Duravr against commercially available transcatheter aortic valve replacements (TAVRs), non-inferiority as a primary study goal, a primary composite endpoint of death, stroke and rehospitalization and inclusion of all patient risk stratifications (high, intermediate, low).

The company said the FDA had “indicated that a single-arm, valve-in-valve registry to run concurrently with the primary aortic stenosis arm [was] also acceptable”.

Anteris said the study would be “the first randomized all risks head-to-head registration trial for TAVR and … [was] expected to generate interest from both the medical and regulatory communities”.

Anteris chief executive officer Wayne Paterson said that feedback from the FDA was “an important milestone as we continue our progress toward study approval and completion”.

“This is the final study on the path to marketing approval for Duravr,” Mr Paterson said.

Anteris said it would submit its pivotal investigational device exemption application, pending completion of FDA-required animal and bench tests.

Anteris was up 14 cents or 0.75 percent to $18.89.

UNIVERSAL BIOSENSORS

Universal Biosensors says it has received $3,790,761 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

The company said the payment related to expenditure in the year to December 31, 2023.

Universal Biosensors fell one cent or 6.9 percent to 13.5 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says the Houston Texas-based Gene by Gene has started US testing of its Genetype genetic risk assessment product series.

Genetic Technologies said that Gene by Gene could process up-to 25,000 tests a month, which “greatly increases Genetype’s operational capacity in North America”, and the “central US” laboratory would shorten the turn-around time for North America samples.

Genetic Technologies fell 0.1 cents or one percent to 9.7 cents.

GENETIC SIGNATURES

Sydney’s Perennial Value Management has increased its substantial shareholding in Genetic Signatures from 23,315,814 shares (12.50%) to 33,476,488 shares (15.55%).

Perennial Funds said it bought and sold shares between January 29 and June 13, 2024 with the single largest acquisition 2,358,126 shares for $1,697,851 or 72.00 cents a share.

Genetic Signatures was up 3.5 cents or 5.2 percent to 71 cents.

GENETIC SIGNATURES

Regal Funds Management has become a substantial shareholder in Genetic Signatures with 14,529,831 shares or 6.75 percent of the company.

The Sydney based Regal Funds said that it acquired 9,085,136 shares between February 29, and June 13, 2024 for $6,591,358 or an average of 72.55 cents a share.

IMMUTEP

Insignia Financial Ltd says it has increased its substantial shareholding in Immutep from 85,419,914 shares (7.49%) to 127,728,455 shares (8.97%).
The Melbourne-based Insignia said that from July 4, 2023 to June 12, 2024 it bought and sold shares with the single largest acquisition 20,363,576 shares for $7,738,159 or 38.0 cents a share
Immutep fell 2.5 cents or 5.95 percent to 39.5 cents with 3.8 million shares traded.

INVEX THERAPEUTICS

Invex says that non-executive director Dr Megan Baldwin will retire from the company, effective on June 30, 2024.
Invex chair David McAuliffe thanked Dr Baldwin for her service since February 2021.
Invex fell 0.2 cents or 2.8 percent to seven cents.