Biotech Daily

Thursday March 17, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: NEUREN UP 14%; ALCIDION DOWN 3%**

*** GARVAN $185m FUND FOR RARE, UNTREATABLE CANCERS**

*** MICRO-X SENDS 4 ROVER X-RAY UNITS TO UKRAINE**

*** 4D LAUNCHES MRFF-FUNDED XV LUNG SCANNER**

*** IMAGION: MAGSENSE AGENT 'SAFE, WELL TOLERATED'**

*** PARADIGM: UK APPROVES OSTEO-ARTHRITIS TRIAL**

*** PHARMAXIS ADDS TAIWAN TO PXS-5505 BONE CANCER TRIAL**

*** CLINUVEL: NEURACTHEL BATCHES FOR REGULATORY APPROVAL**

*** BIOTRON: 'BIT225 EFFECTIVE AGAINST SARS-COV-2, IN MICE'**

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*** EMYRIA HIGH DOSE MARIJUANA CBD EMD-RX7; TRIAL PLANNED**

*** IDT REQUESTS MRNA 'GRANT APPLICATION' TRADING HALT**

*** ORTHOCELL REQUESTS 'REGULATORY APPROVAL' TRADING HALT**

*** RESAPP REQUESTS 'COVID RESULTS' TRADING HALT**

*** PACIFIC EDGE APPOINTS TONY BARCLAY DIRECTOR**

MARKET REPORT

The Australian stock market climbed 1.05 percent on Thursday March 17, 2022, with the ASX200 up 75.6 points to 7,250.8 points. Twenty-nine Biotech Daily Top 40 stocks were up, four fell, six traded unchanged and one was untraded. All three Big Caps were up.

Neuren was the best, up 56 cents or 14.0 percent to $4.56, with 618,000 shares traded. Micro-X climbed 12.1 percent; Dimerix, Emvision, Polynovo and Resonance were up eight percent or more; Paradigm, Starpharma and Volpara improved seven or more percent; Genetic Signatures, Nanosonics and Prescient rose more than six percent; Immutep, Imugene and Kazia climbed more than five percent; Antisense and Compumedics were up four percent or more; Actinogen, Amplia, Impedimed, Pro Medicus and Universal Biosensors were up more than three percent; Avita, Opthea, Resmed and Telix rose more than two percent; Clinuvel, Cochlear, Cyclopharm and Cynata climbed more than one percent; with CSL and Mesoblast up by less than one percent.

Yesterday's 8.6 percent best, Alcidion, led the falls, down 0.5 cents or 2.6 percent to 18.5 cents, with 2.9 million shares traded. Proteomics shed 2.3 percent; Uscom lost one percent; with Medical Developments down 0.5 percent.

THE GARVAN INSTITUTE OF MEDICAL RESEARCH

The Garvan Institute says $185 million invested in its Prospect fund will assist research into rare and untreatable cancers.

The Institute said that the program, called the Precision Oncology Screening Platform Enabling Clinical Trials (Prospect), was funded by $61.2 million from the Federal Government's Medical Products stream of the National Manufacturing Priority, with major investments from Roche Australia, the Australian National Univeristy's National Computational Infrastructure, the Children's Cancer Institute Australia and Dr Andrew 'Twiggy' Forrest's Minderoo Foundation.

The Garvan Institute's executive director Prof Chris Goodnow said the announcement was "underpinned by a decade of research at the Garvan into genomic medicine and cancer".

The Garvan's head of genomic cancer medicine Prof David Thomas said that "genomic medicine allows us to look at the genetics of a person's cancer, rather than treating it based on location, for example breast, colon, skin".

"This allows us to understand inherited cancer risk and find more effective treatments for people with cancer," Prof Thomas said.

"Through Prospect, we will fast-track the development, manufacturing and use of precision, personalized cancer treatments, changing lives, creating jobs and building Australia's sovereign capability in drug development".

The Federal Minister for Health Greg Hunt said the project would help "consolidate patient data to translate those breakthroughs into genomic cancer medicines".

MICRO-X

Micro-X says it has partnered with the Stateline, Nevada-based 'Revived Soldiers Ukraine' to provide four Rover x-ray devices for the Ukraine, at cost price.

Micro-X did not disclose the price of the Rover units.

In a media release not published on the ASX announcements platform, the company said that its "South Australian-designed and produced x-ray technology will be at the forefront of the x-ray needs of Ukraine's medical community in the war against Russia".

Micro-X said it was working with the charity Revived Soldiers Ukraine, which had bought four Rover devices to be used in Ukrainian hospitals.

The company said the Rover was "an ultra-lightweight, highly mobile, medical x-ray machine that delivers easier and simpler x-ray imaging for patients and faster workflow for radiographers".

Micro-X said that the Rover was designed for the Australian military as "an ultra-mobile radiology [product] for military hospitals, delivering the full spectrum of imaging … in support of combat operations or humanitarian aid and disaster relief".

The company said that at 95kg compared with 500kg for a conventional imaging machine, the Rover would be used to support Ukraine's health system.

Mr Hall said Micro-X was able to provide the Rovers to Revived Soldiers Ukraine within 24 hours and they were "on their way to Ukraine, providing invaluable diagnostic equipment for injured people".

"The Rover can be easily manoeuvred through hospital corridors to a patient's bedside in a crowded [intensive care unit], or a military field hospital and more easily and safely positioned by radiographers," Mr Hall said.

"Supporting humanitarian efforts is essential, and we appreciate that the capabilities of the Rover will be able to provide diagnostic services where they're needed most," Mr Hall said.

Micro-X was up two cents or 12.1 percent to 18.5 cents.

4D MEDICAL

4D Medical says it has launched its XV Scanner with the installation of the first system at Sydney's Prince of Wales Hospital today.

Earlier this year, 4D Medical says it would conduct a 40-lung transplantation patient trial with Melbourne's Alfred Health to validate its imaging systems (BD: Jan 24, 2022). Last year, the company said I-Med Radiology Network completed the first commercial respiratory scans using XV lung ventilation analysis software (BD: Dec 9, 2021).

Today, 4D managing-director Dr Andreas Fouras told Biotech Daily that the previous announcements referred to the software that enabled scans over time, whereas today the company installed the first hardware, the complete scanner.

Dr Fouras said the installation was valued at about $1 million, which was part of the $28.9 million in funding from the Federal Government's Medical Research Future Fund.

In a media release to the ASX, 4D said that the XV scanner integrated its XV Technology into a platform "providing doctors and patients with unprecedented and highly visual insight into lung function".

The company said the scanner was delivered ahead of schedule and "increases throughput, reducing costs for healthcare providers, facilitates access to XV technology for more patients, including children and the very unwell unable to be scanned using conventional imaging equipment thereby accelerating uptake of the company's core [service as a software] product".

4D said that all the engineering research and development "was completed in-house in Australia, achieving sovereign capability whilst creating of a significant body of intellectual property that has already generated three patents".

Dr Fouras said the launch of the XV scanner was "completed on time and within budget despite challenges created by the ongoing Covid-19 pandemic".

"From the viewpoint of doctors and patients, the scanner represents a seminal event in the global evolution of respiratory diagnostics and from a commercialization perspective, this scanner creates multiple opportunities to drive adoption of XV technology," Dr Fouras said.

"We are extremely proud that the scanner was designed and manufactured in Australia," Dr Fouras said.

"Its development is another demonstration of 4D Medical's ability to deliver cutting edge technology that can be sold within Australia and exported around the globe," Dr Fouras said.

Lung Foundation Australia chief executive Mark Brooke said the technology "promises to revolutionize diagnostic and imaging procedures for a range of lung diseases impacting children, adults and older Australians".

Separately, a media release from the Federal Minister for Health Greg Hunt said the XV scanner would "change lives, bringing new hope and help for people living with lung conditions such as chronic obstructive pulmonary disease, cystic fibrosis and asthma".

"It will detect disease earlier and more accurately monitor chronic respiratory conditions," the media release said.

Mr Hunt said the Federal Government provided $28.9 million in funding for the development of the XV scanner and "every Australian should be proud of this ground-breaking, Australian-made medical technology platform".

"The development of the XV Scanner is a wonderful example of Australia again punching above its weight in the world of health and medical research," Mr Hunt said.

The Federal Government media release quoted Dr Fouras saying that the XV scanner "would not have been possible without the MRFF investment".

4D was up 14 cents or 19.9 percent to 84.5 cents with 2.1 million shares traded.

IMAGION BIOSYSTEMS

Imagion says an evaluation of the first five patients in its first-in-human study shows that its Magsense breast cancer imaging agent is safe and well tolerated.

Last year, Imagion said it had enrolled the first of about 15 patients in the phase I trial of the Magsense imaging agent as an aid in the staging of for human epidermal growth factor receptor-2 positive (HER2+) breast cancer by detecting if the tumor had spread to the lymph nodes (BD: May 26, 2021).

Today, the study's principal investigator, Monash Health's Dr Jane Fox said "there have been no safety issues reported related to the Magsense HER2 imaging agent and that all patients have tolerated the administration and dosage of the injectable [imaging agent]".

"We have observed that the imaging agent, as administered, is capable of reaching the lymph nodes," Dr Fox said.

Imagion executive chair Bob Proulx said "the results from the first five patients provide sufficient justification for us to continue the study".

The company said it would move forward with activities to support further development and clinical studies, with a view to regulatory submissions.

Imagion was up two cents or 46.5 percent to 6.3 cents with 109.7 million shares traded.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has UK regulatory and ethics approval for its phase III trial of pentosan polysulphate sodium for knee osteo-arthritis.

Paradigm said the UK Medicines and Healthcare Products Regulatory Agency had approved its application for ethics approval, meaning it had all the required approvals to start the trial in the UK.

The company said it had completed the approval process through a pilot program for a combined review of regulatory and ethics applications, and as early adopters it "received additional support and direct communication from the UK regulators, a consolidated regulatory and ethics review, quicker review times and reduced costs".

Paradigm interim chief executive officer Dr Donna Skerrett said the UK approval was "another milestone as we continue to progress with clinical site initiation of our phase III … study in Australia, the US and now in the UK".

Paradigm was up 8.5 cents or seven percent to $1.295.

PHARMAXIS

Pharmaxis says it has added five trial sites in Taiwan for its phase II trial of PXS-5505 for patients with bone marrow cancer myelo-fibrosis.

Last year, Pharmaxis said it had dosed the first of 24 patients in its phase II trial of PXS-5505 for the bone marrow cancer myelofibrosis (BD: Oct 13, 2021).

Today, the company said the five Taiwan sites added to its existing list of 11 active sites in Australia and South Korea, as well as four sites in the US expected to become active in the coming months.

Pharmaxis chief executive officer Gary Phillips said the expansion of sites as "part of a focused effort … to bring patients into the trial and deliver results by the year end".

"I am pleased to report that we now have experience with patients who have had three or more months of therapy on PXS-5505 and that the good tolerability profile is being maintained," Mr Phillips said.

Pharmaxis was unchanged at 8.5 cents.

BIOTRON

Biotron says BIT225 has shown “substantial and clinically meaningful efficacy” against severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2), in mice.

Biotron said that studies at the La Jolla California-based Scripps Research Institute showed that 300mg of oral BIT225 “protected against severe disease indicted by the significant prevention of body weight loss and absence of death in Sars-Cov-2-infected [mice] treated with BIT225 compared to non-treated controls”.

The company said that data showed a pronounced downward trend commencing about day-4 in Sars-Cov-2-infected mice treated with placebo, but not in BIT225 treated mice.

Biotron said that BIT225 “significantly reduced virus levels in the lungs of animals challenged with Sars-Cov-2 [and] the results show statistically and clinically significant efficacy of BIT225”.

Last year, the company said BIT225 had shown “substantial and clinically meaningful efficacy” against Sars-Cov-2 in mice treated for seven days (BD: Nov 25, 2021).

Today, Biotron said the repeat study was extended to 12 days, with no BIT225-treated mice developing “any signs of disease, and all continued to gain weight as per age expectations through to day-12, when the study was terminated”.

The company said that “in contrast, all mice in the control, drug-free group died by day-8 post-infection with Sars-Cov-2 from severe Covid.

Biotron managing-director Dr Michelle Miller said “the results from the extended, repeat study 2 confirm the results from study 1, showing a clear clinical benefit from the treatment with BIT225”.

“Supported by these results, and in consultation with US-based advisors and consultants, Biotron has submitted a proposal to the US Food and Drug Administration to conduct a human clinical trial to assess the efficacy of BIT225 for the treatment of Covid-19 under the Coronavirus Treatment Acceleration Program, a special emergency program for potential coronavirus therapies,” Dr Miller said.

“Funding the clinical development of BIT225 for this indication will be sought from potential partners and non-equity funding sources,” Dr Miller said.

Biotron was up 1.6 cents or 24.6 percent to 8.1 cents with 22.8 million shares traded.

RACE ONCOLOGY

Race says Zantrene in combination with decitabine is ‘highly effective’ against extra-medullary acute myeloid leukaemia, in mice.

Race said the pre-clinical study, at the New South Wales University of Newcastle and run by Prof Nikki Verrills, found that Zantrene, formerly bisantrene, with decitabine targeted extra-medullary tumors as well as those in the bone marrow and spleen.

The company said that on its own, Zantrene killed a genetically diverse range of acute myeloid leukaemia cells at low drug concentrations and slowed the growth of tumors in mice, but the combination of Zantrene and decitabine “showed significantly greater cell killing across a diverse panel of [acute myeloid leukaemia] cell lines than either drug on its own”.

Race chief scientific officer Dr Daniel Tillett said “the results from Prof Verrills’ laboratory are highly supportive of our upcoming [extra-medullary acute myeloid leukaemia] phase I/II trial for Zantrene”.

“The optimized drug combination and schedule identified in this pre-clinical mouse study will be rapidly translated to the clinic via our [extra-medullary acute myeloid leukaemia] trial,” Dr Tillet said.

Race was up 12 cents or 4.6 percent to $2.72 with 405,826 shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says it is increasing test batch manufacturing of adreno-cortico-tropic hormone (ACTH), or Neuracthel, to validate the drug for regulatory approval.
Last year, Clinuvel said it had added Neuracthel to its hormone treatment portfolio and would evaluate its potential for neurological, endocrinological and degenerative disorders (BD: Nov 8, 2021).
Today, the company said the test batches were being created under good manufacturing practice conditions.
Clinuvel was up 39 cents or 1.9 percent to $20.50 with 176,034 shares traded.

EMYRIA

Emyria says it has developed a high dose marijuana-based cannabidiol (CBD) only, prescription-only EMD-RX7 capsules, with a phase I trial planned by the end of 2022.
In January, Emyria said it expected a phase I trial of its over-the-counter EMD-RX5 cannabidiol capsule for psychological distress and irritable bowel syndrome to begin by April (BD: Jan, 20, 2022).
Today, Emyria said that the phase I trial of EMD-RX5 was underway, and that a similar trial for EMD-RX7 was in planning and would begin by the end of the year.
Emyria said both versions would target a dose of one to three capsules a day, but that EMD-RX5 would be sold over-the-counter at lower doses for indications like psychological distress, while EMD-RX7 would be prescription-only for a range of indications requiring higher CBD dosing, including epilepsy, rheumatoid arthritis, social anxiety disorder and insomnia, and graft-versus-host disease.
Emyria was up 2.5 cents or 8.8 percent to 31 cents.

IDT AUSTRALIA

IDT has requested a trading halt “pending the release of an announcement in relation to its… [mRNA] Manufacturing Collaboration Stream Grant application”.
Trading will resume on March 21, 2022, or on an earlier announcement.
IDT last traded up half a cent or 2.6 percent to 19.5 cents.

ORTHOCELL

Orthocell has requested a trading halt “in relation to the regulatory approval of a medical device from the company’s Celgro platform”.
Trading will resume on March 21, 2022, or on an earlier announcement.
Orthocell last traded at 39 cents.

RESAPP HEALTH

Resapp has requested a trading halt “pending the release of an announcement regarding its Covid-19 study results”.
Trading will resume on March 21, 2022, or on an earlier announcement.
Resapp last traded at 6.2 cents.

PACIFIC EDGE

Pacific Edge says it has appointed Tony Barclay an independent non-executive director, effective from March 21.

Pacific Edge said that Mr Barclay was formerly Fisher & Paykel Healthcare chief financial officer and company secretary and was currently the chair of New Zealand's Izon Science and Australia's Baymatob, and a director of New Zealand's Veriphi.

The company said Mr Barclay held a Bachelor of Commerce from New Zealand's University of Otago.

Pacific Edge was up one cent or 1.3 percent to 78 cents.