Biotech Daily

Monday September 19, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: MICRO-X UP 26%; CLINUVEL DOWN 7%**

*** MICRO-X, VAREX $15m NEX X-RAY DEAL; VAREX TO TAKE 9.9%**

*** POLYNOVO WINS US FDA CLEARANCE FOR NOVOSORB MTX**

*** HYDRIX INSTO RIGHTS RAISE $2.1m; RETAIL RIGHTS FOR $4m MORE**

*** AUSTRALIA APPROVES IMUGENE VAXINIA CANCER TRIAL**

*** STUDIES BACK ANTERIS DURAVR HEART VALVES**

*** IMRICOR FILES FOR EURO VENTRICULAR TACHYCARDIA TRIAL**

*** AVECHO: TPM INCREASES CBD BIO-AVAILABILITY, IN DOGS**

*** EMYRIA HIRES PSYCHOGENICS FOR MDMA DRUG DISCOVERY**

*** RESPIRI REQUESTS 'US EXPANSION CAPITAL RAISING' TRADING HALT**

*** CHAIR PAUL RENNIE INCREASES, DILUTED TO 7.2% OF PARADIGM**

*** NOXOPHARM LOSES FOUNDER DR GRAHAM KELLY; HOLDS 13%**

*** MEDIBIO APPOINTS DR THOMAS YOUNG CEO ON $164k PA**

MARKET REPORT

The Australian stock market fell 0.28 percent on Monday September 19, 2022, with the ASX200 down 19.2 points to 6,719.9 points. Eleven of the Biotech Daily Top 40 were up, 19 fell, nine traded unchanged and one was untraded. All three Big Caps fell.

Micro-X was the best, up 3.5 cents or 25.9 percent to 17 cents, with 2.3 million shares traded. Starpharma climbed 20.7 percent on no news; Polynovo improved 10 percent; Dimerix and Universal Biosensors were up seven percent or more; Patrys was up 4.35 percent; Oncosil and Prescient rose two percent or more; Genetic Signatures was up 1.1 percent; with Next Science and Pro Medicus up by less than one percent.

Clinuvel led the falls, down $1.49 or 6.95 percent to $19.94, with 212,740 shares traded. Antisense and Avita lost more than five percent; Cynata fell 4.55 percent; Alcidion, Cyclopharm, Immutep, Medical Developments, Telix and Volpara were down more than three percent; Impedimed, Mesoblast and Neuren shed more than two percent; Cochlear, CSL, Emvision, Orthocell and Paradigm were down one percent or more; with Nanosonics, Opthea, Proteomics and Resmed down by less than one percent.

MICRO-X

Micro-X says it has a $15 million collaboration with Varex Imaging Corporation to licence its Nex multi-beam x-ray tubes, and take a 9.9 percent holding in Micro-X.

Micro-X said that it would provide the Salt Lake City, Utah-based Varex with an exclusive global licence for its Nex multi-beam x-ray tubes for $US5 million ($A7.5 million), payable in five equal milestones over 12 months.

The company said Varex agreed to subscribe for 50,709,000 shares, or 9.9 percent of Micro-X, at 14.7 cents a share, a nine percent premium to the last closing price.

Micro-X said the placement would be in two tranches, with 4.9 percent to be issued within three days, and the remainder on approval from the Foreign Investment Review Board.

The company said the agreement would provide Varex the right to use Micro-X intellectual property to commercialize multi-beam emitter technology, and was limited to x-ray tubes with multiple beams - an application not used in any of Micro-X's four business units.

Micro-X said its commercialization strategy was unchanged as a supplier of high-value products and the deal had "many strategic benefits in maintaining product innovation".

"As part of the collaboration Micro-X will investigate how Varex's photon-counting detectors might extend the performance of its emerging [computed tomography] products," the company said.

Micro-X said that the funds would support ongoing activities as well as final preparations for its Argus product launch.

Micro-X managing-director Peter Rowland said the investment recognized "the value of Micro-X's world-leading technology with Varex, one of the world's most innovative x-ray technology companies, validating the future importance of cold-cathode x-ray technology".

Micro-X was up 3.5 cents or 25.9 percent to 17 cents with 2.3 million shares traded.

POLYNOVO

Polynovo says it has US Food and Drug Administration 510(k) clearance for its Novosorb MTX (matrix) for soft tissue regeneration for complex wounds.

Polynovo chief executive officer Swami Raote told Biotech Daily that MTX was essentially the Novosorb biodegradable temporizing matrix (BTM) "without the temporizing laminate".

"For some of the shallow wound-beds, surgeons use their judgement to remove the temporizing laminate and do a skin-graft directly on BTM, thus avoiding another visit and reducing the cost," Mr Raote said.

The company said that following feedback from surgeons it developed the product to suit their needs and MTX was informed by experience with Novosorb BTM where early removal of the sealing membrane was followed by rapid formation of granulation tissue and wound closure.

Polynovo said that with MTX, the wound could be closed with either a skin graft or allowed to heal by contraction and formation of an epithelial layer, simplifying wound management and common wound healing problems.

The company said MTX was indicated for use in partial and full thickness wounds, pressure ulcers, venous ulcers, chronic and vascular ulcers, diabetic ulcers, and surgical and trauma wounds, providing "greater versatility in wound management".

Polynovo medical director Prof Marcus Wagstaff said that for wounds that do not require temporizing or protection from contraction, there is a clear clinical need for MTX".

"It is best suited in cases where wound contraction and reduced time to healing are preferred, such as diabetic and venous ulcers, and smaller traumatic or post-surgical wounds, for example after excision of skin cancer," Prof Wagstaff said.

Polynovo was up 13.5 cents or 9.96 percent to $1.49 with 5.7 million shares traded.

HYDRIX

Hydrix says it has raised about $2.07 million in the “fully subscribed” institutional component of its one-for-two, non-renounceable entitlement offer at six cents a share.
Last week, Hydrix said it hoped to raise up to $6 million in the institutional and retail rights offer (BD: Sep 15, 2022).
Hydrix fell 1.5 cents or 16.3 percent to 7.7 cents.

IMUGENE

Imugene says a licence from the Australian Government’s Office of the Gene Technology Regulator will expand its Vaxinia phase I cancer trial to Australia.
Imugene said the licence was titled ‘Clinical trial of a genetically modified (GM) chimeric Orthopoxvirus (CF33-hNIS) as a cancer treatment’ and was required as part of Australia’s regulatory framework for dealings involving the intentional release (DIR) of genetically modified organisms into the environment.
In May, the company said it dosed the first of up-to 100 patients, in the trial of CF33-hNIS Vaxinia virotherapy and pembrolizumab for advanced solid tumors, and earlier this month said it had begun dosing the second cohort (BD: May 18; Sep 1, 2022).
Today, Imugene said that the study aimed to recruit 100 patients at about 10 clinical trial sites in Australia and the US, and was expected to run for about 24 months.
Imugene managing-director Leslie Chong said the company was “pleased to see this regulatory hurdle cleared on schedule which will allow the smooth progression of our Vaxinia phase I trial as planned”.
Imugene was unchanged at 22 cents with 14.4 million shares traded.

ANTERIS TECHNOLOGIES

Anteris says two studies presented at the Transcatheter Cardiovascular Therapeutics conference in Boston support the use of its Duravr trans-catheter heart valve.
Anteris said a 13-patient study, titled ‘The Impact of Novel Leaflet Design on Haemodynamics and Transvalvular Physiology: Anteris’ Duravr THV First in Human Study’ showed “100 percent procedural success with no incidence of death, stroke, bleeding, reoperation, reintervention, myocardial infarction, or device deficiency”.
Anteris said that at 30 days the heart valve had “excellent haemodynmaics [with a] mean pressure gradient of 9.02 millimetre of mercury (mmHg), effective orifice area of 2.00cm^2, and extensive mean value leaflet coaptation length of 8.3mm”.
The company said that two-dimensional magnetic resonance imaging (MRI) showed Duravr was the first aortic valve to show restoration of normal laminar flow dynamics.
Separately, the company said a 22-patient study showed its Duravr heart valve had “no significant difference to normal healthy aortic valve flow” but did not provide the data.
Anteris said that when current generation transcatheter aortic valve replacement (TAVR) and surgical aortic valve replacement (SAVR) valves were compared to the healthy aortic valve, both groups demonstrated “statistically significant worse flow”.
Anteris chief medical officer Dr Chris Meduri said the data showed that by shaping the leaflets to mimic the native aortic valve, “we achieve superior haemodynamic performance [and] also restore normal laminar flow which is now demonstrated for the first time”.
Anteris chief executive officer Wayne Paterson said the preliminary data showed that Duravr THV provided flow dynamics equal to a typical healthy native valve and was “superior to current generation TAVR and SAVR haemodynamics”.
Anteris was up 32 cents or 1.25 percent to $25.82.

IMRICOR MEDICAL SYSTEMS

Imricor says it has filed its invasive cardiovascular magnetic resonance-guided (ICMR) ventricular tachycardia ablation clinical trial for approval in Europe.

Imricor said that the study, titled 'Vision-MR Ablation of VT' or Visabl-VT was a 64-patient, prospective, single-arm, multi-centre interventional investigation of the safety and efficacy of radio-frequency ablation of ventricular tachycardia associated with ischemic cardio-myopathy performed with its Vision-MR ablation catheter 2.0 in the invasive cardiovascular magnetic resonance environment.

The company said that the application to begin the trial was submitted to the ethics committee at the Leipzig Heart Centre in Germany, the lead clinical site, as well as the German Federal Institute for Drugs and Medical Devices.

Imricor chair Steve Wedan said the filing was "a major milestone for Imricor that brings us one monumental step closer to treating ventricular tachycardia with ablation procedures guided by real-time ICMR".

"Since this is our first clinical trial submission under the new Medical Device Regulations in Europe, we do not have a clear estimate of how long the approval process will take," Mr Wedan said.

"We are hopeful that we can begin enrolment before the end of the year," Mr Wedan said.

Imricor was up 2.5 cents or 7.8 percent to 34.5 cents.

AVECHO BIOTECHNOLOGY

Avecho says pharmaco-kinetic studies show that tocopheryl phosphate mixture (TPM) increases the bioavailability of cannabidiol (CBD), in dogs.

Avecho said that the study characterized and compared the CBD absorption profile from a single dose of the Avecho TPM-CBD formulation, CBD dissolved in an oil vehicle, the commercial Epidiolex formulation and a formulation with TPM dissolved directly into Epidiolex.

Avecho said that the test formulations were administered to fasted dogs through and oral tube and characterized over 24 hours.

The company said that its TPM-CBD formulation produced a higher absorption profile than the CBD oil control and the Epidiolex formulation.

Avecho said that no symptoms of gastro-intestinal irritation were observed for its formulation for Epidiolex and TPM-CBD, despite the four-times increase in average CBD absorption.

The company said that increased absorption of its cannabidiol formulation had been reproduced in rodents and dogs and the results "validate the company's choice of formulation for use in human trials seeking low dose CBD approval and gives the maximal change of success in the upcoming phase III trial".

Avecho chief executive officer Dr Paul Gavin said the company had shown that TPM formulations "could increase the oral absorption of CBD in rats when compared to simple CBD oil formulations currently prescribed to patients in Australia".

"These formulations are now in clinical trials and will be entering phase III clinical trials for an insomnia related indication," Dr Gavin said.

Dr Gavin told Biotech Daily the comparison with Epidiolex was "because we were frequently asked how our formulations compared to Epidiolex, the only US Food and Drug Administration approved CBD product, despite having a different clinical indication".

Avecho was unchanged at 1.1 cents with 1.2 million shares traded.

EMYRIA

Emyria says it will work with the Paramus, New Jersey-based Psychogenics to help develop its 3,4-methylene-dioxy-meth-amphetamine (MDMA) drug discovery program.
Emyria said that Psychogenics would screen five MDMA analogs developed with the University of Western Australia using its Smartcube drug discovery platform.
The company said that Smartcube used computer vision and artificial intelligence (AI) to extract and analyze behavioral and physiological data from mice to help "predict the clinical effects of new drug compounds by comparing the novel drugs effects to reference drug libraries".
Emyria said that the Smartcube testing platform offered an "effective approach to the discovery and development of the next generation of breakthrough treatments for neurological disorders and [could] significantly reduce the time and cost to reaching approved investigational new drug status".
Emyria said that it would work collaboratively with Psychogenics, at their own costs, in the initial phase, and would explore drug discovery and commercialization partnership models in the future.
The company said that a successful partnership could accelerate the development of its MDMA-inspired drug candidate library into treatments for severe neuro-psychiatric disorders.
Emyria said that approval had already been received from the US Drug Enforcement Agency to transport the initial MDMA-analogues to the US.
Emyria chief executive officer Dr Michael Winlo said the company was "pleased to commence our US-based preclinical program with leading neuroscience clinical research organization, Psychogenics".
"Psychogenics has successfully identified novel treatment candidates for serious and complex neuro-psychiatric disorders via its proprietary Smartcube platform as well as formed innovative partnerships with major pharmaceutical companies," Dr Winlo said.
"Given the increasing research and investment into novel neurological drugs and psychedelic-assisted therapies, we are excited to accelerate the identification of promising neuropsychiatric drugs and next-generation psychedelic-assisted therapies for further evaluation," Dr Winlo said.
Emyria was up two cents or 8.9 percent to 24.5 cents.

RESPIRI

Respiri has requested a trading halt pending an announcement "regarding finalization of an equity raising to support the company's US expansion".
Trading will resume on September 21, 2022 or on an earlier announcement.
Respiri last traded at 4.2 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm chair Paul Rennie says he has increased his substantial holding in Paradigm but been diluted from 20,157,389 shares (8.66%) to 20,391,234 shares (7.15%).
The Adelaide-based Mr Rennie said that with Kzee Pty Ltd on September 14, 2022 he bought 233,845 shares in an entitlement offer for $303,999 or $1.30 a share.
Last week, Paradigm said that its underwritten rights issue at $1.30 a share raised $20.3 million taking the total raised to $66 million (BD: Aug 15; Sep 13, 2022.
Paradigm fell two cents or 1.6 percent to $1.20.

NOXOPHARM

Noxopharm says founder and former chief executive officer Dr Graham Kelly has resigned as a non-executive director, effective from September 20, 2022.
Noxopharm said that the change represented “the natural evolution of the company’s leadership, as it transitions to the next stage of its development”.
Dr Kelly said “my wife and I are the company’s largest shareholders, and that is a position we intend to retain”.
Last year, Dr Kelly and Milligene Pty Ltd said they held 36,162,294 shares (13.16%) with the shares held directly and by Milligene, Phytose Corp, Bende Holdings and Prue Kelly (BD: Mar 1, 2021)
Noxopharm fell two cents or 8.2 percent to 22.5 cents with one million shares traded.

MEDIBIO

Medibio says it has appointed the US-based Dr Thomas Young as its chief executive officer, effective from September 19, 2022, on $327,826 a year.
In June, Medibio said managing-director and chief executive officer Claude Solitario had resigned “to pursue other business interests” (BD: Jun 22, 2022).
Today, the company said the Dr Young would be employed on 0.5 part-time and he would be paid $US110,000 ($A163,928) for the part-time position.
Medibio said that Dr Young had more than 40 years of medical experience and had co-founded the Boise, Idaho-based Nview Behavioural Health, working as chief medical officer and as a director.
Medibio said that previously, Dr Young was Idaho Medicare QIO Qualis Health chief clinical and medical officer, and Idaho Medicaid medical director.
According to his Linkedin page, Dr Young held a Bachelor of Science from Austin College in Texas and a Doctor of Medicine from the University of Texas Medical Branch in Galveston.
Medibio fell 0.05 cents or 33.3 percent to 0.1 cents with two million shares traded.