Biotech Daily

Tuesday August 10, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: NOVA EYE UP 15%; LBT DOWN 7%**

*** EMVISION PORTABLE BRAIN SCANNER READY FOR TESTING**

*** OPTHEA: CANADA APPROVES PHASE III OPT-302 WET AMD TRIAL**

*** CLARITY DOSES 1st PROSTATE CANCER IMAGING TRIAL PATIENT**

*** CLINUVEL: 3 PATIENTS - 'AFAMELANOTIDE SAFE FOR STROKE'**

*** AROA: 'ENDOFORM NATURAL SIGNIFICANTLY BEATS COLLAGEN/ORC'**

*** INCANNEX APPLIES FOR PSILOCYBIN ANXIETY TRIAL**

*** GOODBYE ESENSE**

*** FACTOR EGM TO BECOME POWERLIME**

*** REDMILE REDUCES TO 6.7% OF AVITA**

*** ANDREW CHAPONNEL REPLACES MESOBLAST CFO JOSH MUNTNER**

*** CYCLOPHARM APPOINTS DIANNE ANGUS DIRECTOR**

*** MEDADVISOR: ADHERIS FOUNDER LUCAS MERROW DIRECTOR; EXECS**

*** SUDA APPOINTS DR DEBORA BARTON DIRECTOR**

MARKET REPORT

The Australian stock market was up 0.32 percent on Tuesday August 10, 2021, with the ASX200 up 24.2 points to 7,562.6 points. Twenty-two of the Biotech Daily Top 40 stocks were up, 12 fell and six traded unchanged.

Nova Eye was the best, up 5.5 cents or 15.1 percent to 42 cents, with 413,341 shares traded. Prescient climbed 8.6 percent; Actinogen and Impedimed were up more than six percent; Amplia, Cyclopharm and Next Science were up more than five percent; Mesoblast and Telix improved four percent or more; Compumedics and Uscom were up more than three percent; Dimerix, Immutep and Pharmaxis rose more than two percent; Cynata, Genetic Signatures, Imugene, Kazia, Nanosonics, Paradigm and Pro Medicus were up more than one percent; with Polynovo and Resmed up by less than one percent.

LBT led the falls, down 0.7 cents or seven percent to 9.3 cents, with 725,704 shares traded. Optiscan fell 4.35 percent; Neuren, Patrys, Universal Biosensors and Volpara shed more than two percent; Avita, Orthocell and Starpharma were down one percent or more; with Clinuvel, Cochlear, CSL, Medical Developments and Proteomics down by less than one percent.

EMVISION MEDICAL DEVICES

Emvision says the assembly of its first-generation portable brain scanner has been completed and it is ready for testing.

Last month, Emvision said the device was intended for commercialization to be used in intensive care units, stroke and neurology wards, angiogram suites and emergency departments (BD: Jul 20, 2021).

The company said at that time that the scanner was comparable in size to a cart-based ultrasound unit and could be wheeled to the patient's bedside for point-of-care neuro-imaging, to offer bedside decision support and monitoring capability for stroke patients.

Today, Emvision said the first-generation units would be subject to functional, reliability, software and hardware integration, preliminary safety, performance, compliance and other tests to meet international regulatory standards.

The company said that product suitability for manufacturability, assembly, shipment, environmental impact, use, service and repair would also be assessed.

Emvision chief executive officer, Dr Ron Weinberger said "this is an important milestone for the company".

"Our product represents a game changing opportunity to provide accessible point-of-care neuro-imaging for stroke patients, wherever they are," Dr Weinberger said.

"We are tackling the immense health burden that is stroke, with potential future adjacencies in traumatic brain injury and other neurological disorders," Dr Weinberger said.

"Our device will undergo various tests as we prepare for our next stage of expanded clinical studies," Dr Weinberger said.

Emvision was up 36 cents or 13.7 percent to $2.99 with 451,332 shares traded.

OPTHEA

Opthea says Health Canada has joined the US in approving enrolment to its phase III clinical trials of OPT-302 for wet age-related macular degeneration.

In March, Opthea said it would conduct two randomized, double-blinded, sham-controlled trials, with about 990 patients in each, evaluating OPT-302 in combination with ranibizumab (Lucentis) or OPT-302 with aflibercept (Eylea), compared to ranibizumab or aflibercept alone (BD: Mar 15, 2021).

Today, the company said that in both phase three trials, treatment naïve wet age-related macular degeneration (AMD) patients would be randomized to receive intravitreal administration of 2.0mg OPT-302 once every four or eight weeks in combination with 0.5 ranibizumab or 2.0mg aflibercept, during the first 52 weeks.

Opthea said that the top-line 52-week data from the phase III studies was expected by the end of 2023.

Opthea managing-director Dr Megan Baldwin said that "expanding our global reach for the phase III pivotal program is an important milestone for Opthea and this is the first time clinical trials have been conducted in Canada to investigate OPT-302 in patients with retinal disease".

"We believe that OPT-302, if successful in phase III and approved, has the potential to improve the trajectory of wet AMD disease progression," Dr Baldwin said.

"We are working with regulatory authorities worldwide to initiate the phase III registrational clinical trials as quickly as possible in other countries," Dr Baldwin said.

Opthea said it was applying for regulatory approval for the trials in Europe, South America and the Asia-Pacific.

Opthea was unchanged at $1.24 with 1.1 million shares traded.

CLARITY PHARMACEUTICALS

Clarity Pharmaceuticals says the first of 30 patients has been dosed in its 64-copper-SAR-bis-PSMA imaging trial in patients with confirmed prostate cancer.

In July, Clarity said that it expected to raise $92 million in a fully-underwritten initial public offer at $1.40 a share to develop and commercialize its radio-pharmaceuticals for cancer and list on the ASX under the code CU6, with the offer closing today August 10, and a proposed listing on August 25 (BD: Jul 20, 2021).

Also on July 20, Clarity said it had begun its 'Propeller' trial of 64-Cu SAR-bis-PSMA for prostate cancer at Perth's Genesiscare and Sydney's Nepean Hospital.

Clarity executive chair Dr Alan Taylor said at that time that 64-Cu SAR-bis-PSMA had a combination of two targeting agents attached to the SAR technology.

"The preclinical data to date is compelling, with both higher tumor uptake and greater tumor retention compared to the single targeted products utilized by other radiopharmaceutical products on the market, and we look forward to recruiting our first patient for this trial shortly," Dr Taylor.

Clarity said the 30-patient, phase I, positron emission tomography (PET) imaging trial of participants with confirmed prostate cancer using 64-Cu-SAR-bis-PSMA was a blinded, dose-ranging, non-randomized study prior to radical prostatectomy.

The company said that the primary endpoints of the trial were safety, tolerability and efficacy in the detection of primary prostate cancer compared to histopathology.

The prospectus is available at: link https://events.miragle.com/clarity-ipo.

Clarity is currently a public unlisted company.

CLINUVEL PHARMACEUTICALS

Clinuvel says that three stroke patients treated with afamelanotide had no significant side effects with two patients significantly improved in the "world first clinical trial".

Clinuvel said that two patients showed improvement in neurological deficit, while one patient showed no improvement.

The company said that all three patients in the six-patients CUV801 trial had a cardiovascular history prior to the stroke.

Clinuvel said that the patients had acute strokes due to a clot formed in the higher regions of the brain and were treated with frequent afamelanotide doses at a specialist neurological hospital.

The company has previously said that its Scenesse for erythropoietic protoporphyria (EPP) comprised 16mg afamelanotide.

Today, Clinuvel said that none of the patients had drug-related adverse events and all three had been discharged from critical care.

Clinuvel head of clinical operations Dr Pilar Bilbao said that stroke patients with a cardiovascular condition were able to receive afamelanotide "without significant adverse reactions".

"On the basis of the first three patients, there is a prospect that Clinuvel will be able to treat many more stroke patients than initially anticipated, since one third of stroke patients globally have underlying heart problems," Dr Bilbao said.

"In being the first to use a melanocortin in stroke patients, our team and physicians observe the tolerance to frequent dosing of afamelanotide in patients who suffer a life-threatening condition," Dr Bilbao concluded.

Clinuvel fell 15 cents or 0.55 percent to $26.89 with 105,939 shares traded.

AROA BIOSURGERY

Aroa says the first large retrospective analysis shows its Endoform Natural has significantly better healing efficacy than standard collagen/oxidized regenerated cellulose.
The study, titled 'Retrospective real-world comparative effectiveness of ovine forestomach matrix and collagen [and oxidized regenerated cellulose] in the treatment of diabetic foot ulcers' was published in the International Wound Journal and was available at: https://onlinelibrary.wiley.com/doi/10.1111/iwj.13670.
The study abstract said that it compared the healing outcomes of diabetic foot ulcers treated with either ovine forestomach matrix (n = 1150) or collagen/oxidised regenerated cellulose (ORC) (n = 1072) in out-patient wound-care centres.
The abstract reported that the median time to wound closure was significantly faster (p = 0.0015) in the Aroa group (14.6 ± 0.5 weeks) relative to the collagen/ORC group (16.4 ± 0.7).
The study said that a sub-group analysis showed that diabetic foot ulcers treated with the Endoform Natural healed up to 5.3 weeks faster in challenging wounds and the percentage of wounds closed at 36 weeks was significantly improved in Endoform Natural treated ulcer relative to the collagen/ORC.
The abstract said that Endoform Natural-treated wounds had an 18 percent greater probability of healing versus wounds managed with collagen/ORC, and the probability increased to 21 percent when the analysis was adjusted for multiple variables.
Aroa said that diabetic foot ulcers were "the leading cause of non-traumatic amputations in the US and … cost the US health care system $US9-13 billion a year.
Aroa chief executive officer Dr Brian Ward said the study showed "the potential for improvements in patient quality of life due to the significantly reduced time to close wounds and material cost reductions using Endoform Natural compared to traditional collagen dressings".
"This data also adds to our existing body of evidence about the effectiveness and broad application of our Aroa [extra cellular matrix] technology platform for healing complex wounds in compromised patients," Dr Ward said.
Aroa fell 1.5 cents or 1.4 percent to $1.07.

INCANNEX HEALTHCARE

Incannex says, that with Monash University, it has applied for ethics approval for a 72-patient, phase II trial of psilocybin with therapy for generalized anxiety disorder.
Incannex said it also submitted a request to the US Food and Drug Administration for a pre-investigation new drug application meeting, for the randomized, blinded, active-placebo-controlled trial, prepared with regulatory advisors Camargo Pharmaceuticals.
The company said the applications followed the trial design process led by Monash University psychedelic research head and principal investigator Dr Paul Liknaitzky.
Incannex said the trial was planned to begin in 2021 with a phase IIb trial in 2022.
The company said participants would have two psilocybin or active-placebo dosing sessions and up to 11 non-drug, psychotherapy sessions over 10 weeks, at Melbourne's Monash University, Melbourne.
Incannex said the primary outcomes from the trial were safety, efficacy and tolerability, with secondary outcomes quality of life, functional impairment, and comorbidities.
Incannex said a preliminary analysis would be conducted after 30 patients completed the primary endpoint assessment, which would allow the investigators to inform the second part of the trial and/or the follow-up phase IIb clinical trial.
Incannex was up one cent or 3.8 percent to 27.5 cents with 3.3 million shares traded.

ESENSE-LAB

The ASX says that Esense was to be removed from the Official List of the ASX at the close of trading today.
Esense said that last week shareholders passed a special resolution to delist the company from the Official List (BD: Aug 9, 2021).
Esense was in a suspension and last traded at 1.8 cents.

FACTOR THERAPEUTICS

Factor says it will hold an extraordinary general meeting in relation to the acquisition of Powerlime Inc.
Last month, Factor said it would acquire all issued Powerlime shares, move to the resources sector and rename itself Dominion Minerals (BD: Jul 27, 2021).
Today, Factor said investors would vote on the change to nature and scale of activities and issue consideration and management shares and options, as well as the issue of shares and options to related parties and appoint directors.
Factor said that online meeting would be held on September 9, 2021, at 1pm (AEST).
Factor was in a suspension and last traded at 0.5 cents.

AVITA MEDICAL

Avita says that the Redmile Group LLC has reduced its substantial shareholding from 2,001,787 shares (9.32%) to 1,668,327 shares (6.70%).
Avita said that the San Francisco-based Redmile previously said the securities were owned by certain private investment vehicles and/or separately managed accounts managed by Redmile Group.
Avita said the to the best of its knowledge the Bellevue, Washington-based Blackcrane Capital LLC had ceased to be a substantial shareholder.
Avita fell five cents or 0.97 percent to $5.10 cents.

MESOBLAST

Mesoblast says it has appointed Andrew Chaponnel as its interim chief financial officer replacing Josh Muntner, effective from August 30, 2021.
Mesoblast said Mr Muntner would finalise the 2020-’21 financial statements and effect an orderly transition.
The company said Mr Chaponnel had worked for Mesoblast for nine years, as group financial controller and head of finance.
Mesoblast was up nine cents or 4.6 percent to $2.03 with 3.0 million shares traded.

CYCLOPHARM

Cyclopharm says it has appointed Dianne Angus as a non-executive director, effective from August 10, 2021.
Cyclopharm said Ms Angus was previously an executive at Prana (Alterity) and Florigene, was currently a director at Imagion and Neuren and was a registered patent attorney.
The company said that Ms Angus held a Bachelor of Science from the University of Melbourne, a Master of Science from Monash University and a Graduate Diploma in Intellectual Property Law from the University of Melbourne.
Cyclopharm was up 8.25 cents or 5.2 percent to $1.665.

MEDADVISOR

Medadvisor says it has appointed Adheris co-founder Lucas Merrow as a US-based non-executive director.
Medadvisor said Mr Merrow was the cofounder of the now Medadvisor-owned, Adheris as well as co-founder of the Danvers Massachusetts-based Eliza Corp.
The company said Mr Merrow held a Bachelor of Electrical Engineering from Massachusetts Institute of Technology and a Master in Business Administration from the Harvard Business School.
Medadvisor said sales general-manager Wayne Marinoff had been promoted to executive general-manager of sales and marketing, and the executive general-manager of people and culture Ruba El-Afifi had been promoted to chief operating officer.
Medadvisor was up 1.5 cents or 4.5 percent to 35 cents.

SUDA PHARMACEUTICALS

Suda says it has appointed Dr Debora Barton as an independent, non-executive director.
Suda said Dr Barton had more than 20 years' experience in oncology as a physician and clinical trial investigator.
The company said Dr Barton worked for Novartis and Celgene for five years, each.
Suda said Dr Barton was currently Charisma Therapeutics chief medical officer and a member of the Manhattan Board of Directors for the American Cancer Society and the medical advisory board member of breast cancer advocacy group, the Tigerlily Foundation.
According to her Linkedin page Dr Barton said she held a Doctor of Medicine the Sao Paolo, Brazil-based Pontificia Universidade Católica.
Suda was up half a cent or 9.6 percent to 5.7 cents with 2.8 million shares traded.