Biotech Daily

Tuesday November 12, 2024

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: EMVISION UP 12%; RESONANCE DOWN 6%**

*** WEHI 'CURES 1st TOXIC EPIDERMAL NECROLYSIS PATIENTS'**

*** EMVISION: 'STROKE TEST 92% SPECIFICITY, 85% SENSITIVITY'**

*** ARTRYA 'COMMITMENTS' FOR $5m PLACEMENT**

*** GENSCRIPT TO OPEN SYDNEY OPERATIONS HUB**

*** NEUROTECH: 'NTI164 BEATS CBD FOR BRAIN PROTECTION, IN-VITRO'**

*** LTR, RSHC PARTNER FOR SPONTAN TELEHEALTH**

*** ACTINOGEN RECEIVES $9m FEDERAL R&D TAX INCENTIVE**

*** NOXOPHARM RECEIVES $2.3m FEDERAL RDTI; REPAYS $1.9m LOAN**

*** PYC 10-1 CONSOLIDATION DATES**

*** EMYRIA PLEADS 'SCHULTZ, TRUMP' TO ASX 42% PRICE QUERY**

*** NYRADA AGM DEFEATS CHAIR, DIRECTOR OPTIONS**

*** CHIMERIC AGM 24% OPPOSE CHAIR PAUL HOPPER OPTIONS**

*** CHIMERIC COO DR REBECCA MCQUALTER TO CEO; ON $350k PA**

MARKET REPORT

The Australian stock market fell 0.13 percent on Tuesday November 12, 2024, with the ASX200 down 10.6 points to 8,255.6 points. Nineteen of the Biotech Daily Top 40 companies were up, 12 fell and nine traded unchanged.

Emvision was the best (see below), up 21.5 cents or 12.0 percent to $2.00, with 89,586 shares traded. Curvebeam climbed 10 percent; Amplia and Cynata were up more than six percent; Avita, Neuren, Orthocell and Universal Biosensors improved four percent or more; Aroa and Mesoblast were up more than three percent; Micro-X and Pro Medicus rose two percent or more; Cyclopharm, EBR, Immutep and Nanosonics were up one percent or more; with Clinuvel, Opthea, Polynovo, Resmed and Telix up by less than one percent.

Resonance led the falls for a second day in a row, down 0.25 cents or 6.2 percent to 3.8 cents, with 423,418 shares traded. Starpharma shed 5.7 percent; 4D and Syntara fell four percent or more; Medadvisor lost 3.8 percent; Medical Developments and SDI shed more than two percent; Compumedics, Impedimed, and Percheron were down more than one percent; with Clarity, Cochlear, CSL and Genetic Signatures down less than one percent.

WALTER AND ELIZA HALL MEDICAL RESEARCH INSTITUTE

The Walter and Eliza Hall Institute says it has “cured” seven patients with the rare and potentially fatal skin disease, toxic epidermal necrolysis, “for the first time”.

WEHI said a study identified hyper-activation of the inflammatory Janus kinase pathway which could be “targeted with an existing class of drugs, marking the first ever cure for the life-threatening condition”.

The Institute said toxic epidermal necrolysis was “a life-threatening condition that causes widespread blistering and detachment of the skin, often requiring hospitalization” with an about 30 percent mortality rate.

WEHI said the condition was “triggered by an extremely severe adverse reaction to common medications, such as allopurinol, used to treat gout, and certain over-the-counter antibiotics”.

The Institute said that by the time patients presented to hospital with the disease their symptoms were “already at a critical stage, requiring similar treatment to burns victims, including intensive care and life support”.

WEHI said a study conducted with the Munich, Germany-based Max Planck Institute of Biochemistry used deep visual proteomics to analyze skin samples from patients with the skin disease.

The Institute said deep visual proteomics allowed researchers “to zoom in on individual cells and study them in unprecedented detail, creating a map of the thousands of proteins that drive this deadly disease”.

The study, titled ‘Spatial proteomics identifies JAKi as treatment of a lethal skin disease’, was published in Nature and was available at: https://bit.ly/40Km0oy.

Max Planck Institute researcher and first author of the study Dr Thierry Nordmann said applying spatial proteomics to archived patient samples suffering from toxic epidermal necrolysis led to isolating and analyzing individual cell types and understanding what is occurring in the skin of patients.

“We identified a striking hyper-activation of the inflammatory [Janus kinase signal transduction and transcription activation] JAK/STAT pathway, revealing an opportunity to intervene in this deadly condition with JAK inhibitors,” Dr Nordmann said.

WEHI said the theory was tested across multiple pre-clinical studies, including in a disease-approximating mouse-model developed by its researcher and second study author Dr Holly Anderton.

The Institute said that the “overwhelmingly positive results from these studies allowed researchers to proceed directly to trialing the treatment in … patients”.

WEHI said researchers hoped “the milestone findings would … pave the way for a clinical trial aimed at the regulatory approval of JAK inhibitors as a cure for [toxic epidermal necrolysis]”.

Dr Anderton said that “finding a cure for lethal diseases like this is the holy grail of medical research”.

“I am beyond proud of this incredible research collaboration that has already helped to save the lives of multiple patients,” Dr Anderton said.

“All seven people treated with this therapy in our study experienced rapid improvement and a full recovery, in staggering results that has likely unlocked a cure for the condition,” she said.

“It can take a patient weeks to recover from the damage, even after they’ve stopped taking the medication that triggered the adverse reaction,” Dr Anderton said.

“Being able to rapidly halt progression of this disease, as we have seen in our study, will make a huge difference to the standard of care for patients diagnosed with this life-threatening condition,” Dr Anderton said.

EMVISION MEDICAL DEVICES

Emvision says a 307-participant study shows its Emu brain scanner algorithm had 92 percent specificity and 85 percent sensitivity for diagnosing haemorrhagic strokes.

Last year, Emvision said it had scanned all 30 participants in its stage one, healthy volunteer trial of its brain scanner at Sydney's Liverpool hospital; and later, said it had begun its up-to 150-patient, stage two trial (BD: Feb 1, May 29, 2023).

Earlier this year, the company said it had enrolled all 180 patients in its stage two study of its artificial intelligence-based 'Emu' portable brain scanner for stroke and stroke mimic patients in emergency departments; and in May, said stage two confirmed the algorithm could "help answer the clinical question of ischaemia or not" (BD: May 27, 2024).

In July, Emvision said it had recruited its target of 30 haemorrhagic stroke patients in stage three of the trial as well as "a large number of ischaemic stroke participants", with results expected this year (BD: Jul 8, 2024).

Today, the company said the device had 85 percent sensitivity and 78 percent specificity for diagnosing patients with ischemic strokes.

Emvision said a total of 307 participants were enrolled and scanned in the trial, including 277 suspected stoke patients with 48 haemorrhage, or brain bleed, and 140 ischaemic, or blood clot, confirmed strokes.

The company said the study's primary endpoint of collecting matched Emvision Emu and computed tomography (CT) and, or magnetic resonance imaging (MRI) "ground-truth brain scans, for the advancement of the device's [artificial intelligence]-based diagnostic 'blood or not' and 'clot or not' algorithms was achieved".

Emvision said 240 participants' scan data was used to train the device's artificial intelligence algorithms which allowed it to "learn patterns and features associated with a normal versus abnormal brain, including hyperacute, acute, subacute and chronic ischaemic and haemorrhagic stroke".

The company said the device correctly diagnosed 12 of 13 haemorrhage stroke cases and 47 of 55 strokes as not haemorrhage.

Emvision said the algorithm identified 17 of 20 ischaemic stroke cases and 25 of 32 cases found to be not ischaemic strokes.

The company said case studies from the trial showed "exceptional sensing capabilities, including successful detection and classification of very small haemorrhages such as a thalamic haemorrhage of 0.7 milliliters (mL) and a subarachnoid haemorrhage of 1.7mL".

Emvision said the artificial intelligence-based diagnostic models showed "steadily improved performance as additional clinical training data was provided".

The company said the results would be used to begin a "validation trial, as planned, where diagnostic performance of the portable brain scanner will be definitively demonstrated to support … [US Food and Drug Administration] de-novo clearance".

Emvision said it had "site visits scheduled this month with its prospective US investigational sites".

The company said the validation trial would be funded from cash reserves, was expected to cost about $4 million and to take about six-to-12 months.

Emvision managing-director Scott Kirkland said there was "a huge unmet need for stroke and stroke type diagnosis at the point-of-care".

"We are very proud of these results which highlight our technology's unique neuro-diagnostic capabilities," Mr Kirkland said.

"We remain focused on progressing and executing our clinical validation and commercialization strategy as we look to … make a substantial positive impact on one of the major causes of global disability," Mr Kirkland said.

Emvision was up 21.5 cents or 12.0 percent to $2.00.

ARTRYA

Artrya says it has “binding commitments” to raise $5 million at 42.0 cents a share in a placement to “sophisticated and progressional investors”.
Artrya said the placement price was a 17.9 percent discount to the five-day volume weighted average price and a 16.0 percent discount to the last closing price.
The company said the placement was “strongly supported with demand in excess of the funds sought” by investors including US hospital system Tanner Health.
Artrya said the funds would be used for research and development, regulatory work, information technology and security and working capital in preparation for US Food and Drug Administration clearance of its Salix coronary anatomy product.
The company said Petra Capital was sole lead manager and bookrunner to the raise.
Artrya fell 2.5 cents or five percent to 47.5 cents.

GENSCRIPT BIOTECH

Genscript Biotech says it will open a Sydney operations site and logistics centre for its contract development and manufacturing services.
A media release yesterday from the New Jersey-based and Hong Kong Stock Exchange-listed Genscript said it was founded in 2002 and provided contract development and manufacturing services to 200,000 customers in 100 countries with 5,060 employees.
The company said the site would offer “next-day shipping for high-demand products such as off-the-shelf mRNA, growth factors, Cas proteins and more”.
Genscript chief executive officer Sherry Shao said that opening a logistics hub in Sydney would allow the company “to deliver more localized support to our Australian partners”.
“By removing import barriers and offering next-day delivery on key products, we are helping our customers focus entirely on advancing their research, without the logistical challenges that previously existed,” Ms Shao said.
On the Hong Kong Stock Exchange last night, Genscript fell four Hong Kong cents (0.8 Australian cents), or 0.4 percent to $HK10.96 ($A2.15) with 6.9 million shares traded.

NEUROTECH INTERNATIONAL

Neurotech says that in-vitro research shows the anti-inflammatory and neuro-protective effects of its NTI164 marijuana are “enhanced” compared to cannabidiol (CBD) alone.
Last month, Neurotech said the US Food and Drug Administration denied its orphan drug status application for NTI164 for paediatric neuro-psychiatric disorders (BD: Oct 4, 2024).
Today, the company said the study showed “inflammation-induced up-regulation of microglial inflammatory markers was significantly attenuated by NTI164, but not by CBD”.
Neurotech said “NTI164 promoted undifferentiated neuron proliferation and differentiated neuron survival under excitotoxic conditions”.
The company said the results suggested the anti-inflammatory and neuro-protective effect of NTI164 was “likely due to the synergistic interaction of the highly purified and reproducibly manufactured cannabinoids comprising NTI164 rather than isolated CBD”.
Neurotech said that the data emphasized “the potential therapeutic efficacy of NTI164 for disorders associated with persistent or progressive neuroinflammation”.
The study titled, ‘Evaluation of the Efficacy of a Full-Spectrum Low-THC Cannabis Plant Extract Using In Vitro Models of Inflammation and Excitotoxicity’ was authored by the Royal Melbourne Institute of Technology’s Dr Bobbi Fleiss, was published in Biomolecules and was available at: https://bit.ly/4fHMXxl.
Neurotech was up 0.1 cents or 1.85 percent to 5.5 cents.

LTR PHARMA

LTR says with Perth's Restorative Sexual Health Clinic (RSHC) Pty Ltd it will establish an "online men's health platform" for selling therapeutic services and prescriptions.
LTR said the joint venture would use the Restorative Sexual Health Clinic's "expertise in men's healthcare to provide Australian men with convenient access to healthcare professionals, therapeutic services, and prescription treatments".
In August, LTR said the first erectile dysfunction patients had been dosed with its Spontan nasal spray version of vardenafil, marketed by Bayer as Levitra, under the Australian Therapeutic Goods Administration's special access scheme, (BD: Aug 5, 2024).
Today, LTR said that the online platform would offer professional medical consultations, comprehensive therapeutic services, prescription and non-prescription treatments [as well as] integrated health management solutions".
The company did not disclose the commercial terms of the deal, with the joint-venture expected to launch by April 2025.
LTR chair Lee Rodne said that the joint was "a significant milestone in LTR's strategic commercialization plan".
"By partnering with an established leader in men's health services, we are well positioned to meet the growing demand for accessible healthcare solutions," Mr Rodne said.
"The online platform will provide a discrete and convenient channel for men to access professional healthcare services and prescribed treatments," Mr Rodne said.
LTR was up 2.5 cents or 1.6 percent to $1.56 with 881,048 shares traded.

ACTINOGEN MEDICAL

Actinogen says it has received $9,034,351 from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.
Actinogen said the incentive related to its research and development expenditure for the year to June 30, 2024, with the funding to be used for its 220-participant phase IIb/III clinical trial in Alzheimer's disease.
Actinogen was unchanged at 2.4 cents with 7.2 million shares traded.

NOXOPHARM

Noxopharm says it has received $2,342,935 from the Australian Tax Office under the Federal Government's Research and Development Tax Incentive program.
Noxopharm said the incentive related to research and development expenditure for the year to June 30, 2024.
The company said of the total funds received it had used $1,873,421 to repay the principal and interest for its Endpoint Capital loan (BD: Sep 6, 2024).
Noxopharm was up 1.5 cents or 14.3 percent to 12 cents.

PYC THERAPEUTICS

PYC says its 10-to-one consolidation will have a record date of November 18, with post-consolidation trading expected on November 28, 2024 (BD: Oct 15, 2024).
Last month, PYC said its annual general meeting would vote on a 10-to-one stock consolidation (BD: Oct 15, 2024).
Today, the company said that following its 10-to-one consolidation its 4,666,083,409 shares on issue would become 466,608,341 shares.
PYC was unchanged at 19.5 cents with 2.7 million shares traded.

EMYRIA

Emyria has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 41.9 percent from a low of 3.1 cents yesterday to a high of 4.4 cents today and noted a "significant increase in the volume of shares traded.

Emyria said there had been "recent media speculation regarding potential policy shifts by the incoming Trump administration in the US, which may favor the use of psychedelics in therapeutic settings".

The company said that "the media speculation is uncertain and in any event, concerns the industry as a whole rather than Emyria in particular".

Emyria said it was "the only ASX-listed company actively involved in the provision and evaluation of psychedelic-assisted therapies and the company recently … received ethics endorsement for its new psilocybin-assisted therapy program" (BD: Oct 28, 2024).

The company said it was "not aware of any other explanation for the recent trading activity in its securities".

Emyria was up 0.1 cents or three percent to 3.4 cents with 3.7 million shares traded.

NYRADA

Nyrada says 62 percent of its annual general meeting opposed issuing options to chair John Moore and directors Christopher Cox, Marcus Frampton and Dr Rüdiger Weseloh.

Earlier this year, Nyrada said that its general meeting would vote to issue 3,600,000 options to Mr Moore and 1,800,000 options each to Mr Cox, Mr Frampton and Dr Weseloh, each (BD: Sep 30, 2024).

Today, the company said the four resolutions to issue its chair and directors options were all opposed by 33,952,795 votes (61.88%), with 20,915,860 votes (38.12%) in support.

Nyrada said the approval of the approval of the future issue of securities faced 0.27 precent dissent, with the remaining resolutions, including the election of its chair and directors, all unanimously passing with 100 percent of the meeting in favor.

According to its most recent filing, Nyrada had 209,625,366 Chess depository interests on issue, meaning that the 33,952,795 votes against the options amounted to about 16.2 percent of the company, sufficient to requisition extraordinary general meetings.

Nyrada was unchanged at 11 cents with 1.99 million shares traded.

CHIMERIC THERAPEUTICS

Chimeric says its annual general meeting passed all resolutions but with up-to 24.38 percent opposition to the issue of incentive options to chair Paul Hopper.

Last month, Chimeric said the meeting would vote to issue 11,580,882 incentive options to Mr Hopper, in addition to his $250,000 yearly pay (BD: Oct 15, 2024).

Today, the company said Mr Hopper's options were opposed by 20,500,587 votes (24.38%), with 63,588,798 votes (75.62%) in support.

Chimeric said the adoption of the remuneration report faced 16.03 percent dissent, with all other resolutions passed with between 92.66 percent and 97.31 percent of the meeting in support.

According to its most recent filing, Chimeric had 995,140,820 shares on issue, meaning that the 20,500,587 votes against Mr Hopper's options amounted to about 2.1 percent of the company, not sufficient to requisition extraordinary general meetings.

Chimeric was unchanged at one cent with 3.35 million shares traded.

CHIMERIC THERAPEUTICS

Chimeric says it has appointed chief operating officer Dr Rebecca McQualter as its chief executive officer, effective from November 12, 2024, on $350,000 a year.

Chimeric said Dr McQualter's $350,000 fixed annual salary excluded superannuation.

Earlier this year, the company said that it had appointed Dr McQualter as chief operating officer, on a salary of $300,000 a year (BD: May 2, 2024).

At that time, Chimeric said Dr McQualter had been Novartis Australia head of strategic access and had worked for Bioverativ, Amgen and Glaxosmithkline.

According to her Linkedin page Dr McQualter held a Bachelor of Science and a Doctor of Philosophy from Melbourne's Monash University.