Biotech Daily

Wednesday March 19, 2025

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: IMUGENE UP 14%; MEDADVISOR DOWN 9%**

*** ISLAND RIGHTS OPTIONS RAISE $2m; TOTAL $2.7m**

*** EMVISION, FLYING DOCTOR STROKE SCANNER**

*** POLYNOVO NOVOSORB MTX CLEARED IN US, AUSTRALIA, INDIA**

*** IMUGENE FDA AZER-CEL FAST TRACK STATUS**

*** BLINKLAB, VRIJE AMSTERDAM UNI, AUTISM REGISTER TEST STUDY**

*** RHYTHM 1st GENETYPE TEST SALES**

*** BIOXYNE REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** CAMBIUM DILUTED TO 13.5%**

*** IMRICOR 'CAPITAL RAISING' HALT TO SUSPENSION**

*** OPTHEA TAKES 'TRIAL RESULTS' HALT TO SUSPENSION**

MARKET REPORT

The Australian stock market fell 0.41 percent on Wednesday March 19, 2025, with the ASX200 down 32.1 points to 7,828.3 points.

Nineteen of the Biotech Daily Top 40 companies were up, 14 fell, five traded unchanged and two were untraded. The four Big Caps were mixed.

Imugene was the best, up 0.5 cents or 14.3 percent to four cents, with 97.15 million shares traded. Resonance rose 9.8 percent; Amplia, Nova Eye and SDI climbed five percent or more; Compumedics, Emvision and Medical Developments were up four percent or more; Avita, Genetic Signatures, Immutep and Starpharma were up more than three percent; 4D Medical, Clinuvel, Cyclopharm, Dimerix, EBR, Prescient and Telix rose two percent or more; CSL was up 1.05 percent; with Cochlear up 0.4 percent.

Medadvisor led the falls, down one cent or 9.1 percent to 10 cents, with 2.2 million shares traded. Aroa, Atomo and Clarity fell more than five percent; Micro-X and Syntara lost more than three percent; Alcidion, Polynovo and Proteomics shed two percent or more; Mesoblast and Paradigm were down more than one percent; with Nanosonics, Neuren, Orthocell, Pro Medicus and Resmed down by less than one percent.

ISLAND PHARMACEUTICALS

Island says it has raised $1,941,586 through the exercise of options from its March 2024 rights issue, in addition to a previous $779,413, for a total $2,720,999.
Last year, Island said it raised $1.95 million at 6.0 cents a share in its two-for-five rights offer with investors to receive one attaching option exercisable at six cents each within 12 months from the rights offer closing date, and an additional option for each option that was exercised within three months of the closing date (BD: Mar 19, 2024).
Today, the company said 12,990,209 options were exercised within three months of the right issue closing date and 32,359,769 options were exercised within 12 months.
Island said the additional funds raised from the options would support the ongoing clinical development of ISLA-101 as a treatment of dengue fever.
Island was up half a cent or 2.9 percent to 17.5 cents.

EMVISION MEDICAL DEVICES

Emvision says with the Royal Flying Doctor Service it has run a series of volunteer scans using its proof-of-concept, First Responder device for diagnosing stroke.
Emvision said the aero-medical testing was conducted with the Australian Stroke Alliance, with Royal Flying Doctor Service (RFDS) staff receiving preliminary training on its device.
The company said the device aimed to "address significant unmet need in stroke and traumatic brain injury care" by enabling earlier triage, transfer or treatment decisions at the point-of-care.
Emvision said that the First Responder device was "an opportunity to fundamentally transform stroke and traumatic brain injury (TBI) outcomes, regardless of their location, by delivering sophisticated neurodiagnostic technology directly to the patient at their first interaction with the healthcare system".
"'Time is brain' in both stroke and TBI care, meaning the longer a stroke or bleeding goes untreated, the more brain cells die," the company said.
Emvision said the scans showed the device had "an ability to withstand the physical stress, environmental conditions and operational constraints unique to aero-medical retrieval".
The company said it had submitted an ethics approval for a usability and workflow implementation study of the scanner with the RFDS, which was under review.
Emvision said that RFDS staff would enrol and scan patients in the coming weeks, evaluating the device's "usability, reliability, functionality, workflow metrics and other tests as necessary to meet user and international regulatory requirements".
The company said the study would be conducted with Medstar's South Australia Ambulance Service, South Australia Health's Rural Support Services, the Royal Adelaide Hospital and the Australian Stroke Alliance.
Emvision said "product development activities were underway to transition from advanced prototype [proof-of-concept] devices to production equivalent commercial devices".
The company said it had filed a further ethics application with to study its device with the Melbourne Mobile Stroke Unit "during pre-hospital emergency response to acute suspected stroke patients", while gathering computed tomography-scan data.
Emvision managing-director Scott Kirkland said the company was "thrilled to have successfully taken the Emvision First Responder [proof-of-concept] device into the field for the first time".
Mr Kirkland said the studies were "a key step" for the First Responder device, and would help progress to production equivalent commercial units.
Emvision was up 7.5 cents or 4.2 percent to $1.875.

POLYNOVO

Polynovo says it has clearance for up-to six-millimetre thick Novosorb MTX in the US, with further indications, as well a two-millimetre version in Australia and India.

Polynovo said the US Food and Drug Administration granted 510(k) clearance for Novosorb MTX up-to six millimetres and had added tunneled and undermined wounds as additional indications.

The company said the approval would "offer healthcare professionals greater versatility in management of deep soft tissue defects and expand the use of Novosorb MTX into plastic and reconstructive surgery applications".

Polynovo said Novosorb MTX with a two-millimetre thickness had marketing and sales approval by the Australian Therapeutics Goods Administration as well as India's Central Drugs Standard Control Organisation.

Polynovo said Novosorb MTX used the Novosorb BTM technology without a sealing membrane, developed for use in indications where the membrane was not required.

Polynovo chair David Williams said the availability of the product in Australia and elsewhere would "be welcome news to plastic surgeons, amongst others".

Polynovo fell three cents or 2.35 percent to $1.245 with 5.1 million shares traded.

IMUGENE

Imugene says the US Food and Drug Administration has granted fast track designation for its CAR T-cell 'azer-cel' for relapsed or refractory diffuse B-cell lymphoma.

In 2023, Imugene said it would acquire 'azer-cel', or azercabtagene zapreleucel, CD19 chimeric antigen receptor (CAR) T-cell therapy for blood cancers (BD: Aug 16, 2023).

Today, the company said the designation would "expedite the review of drugs that address serious or life-threatening conditions and meet an unmet medical need".

Imugene said diffuse B-cell lymphoma was "the most common and aggressive form of non-Hodgkin's lymphoma, with a significant portion of patients experiencing relapse or resistance to standard treatments".

Imugene managing-director Leslie Chong said the approval was "a testament to the transformative potential of azer-cel for patients battling relapsed or refractory [diffuse large B-cell lymphoma]".

Imugene was up half a cent or 14.3 percent to four cents with 97.15 million shares traded.

RHYTHM BIOSCIENCES

Rhythm says it has its first commercial sale of the Genetype risk assessment test since acquiring it from Genetic Technologies in December last year.

Last year, Rhythm said would acquire Genetic Technologies' Genetype risk assessment test for various diseases for $625,000 in cash (BD: Jan 19, 2025).

The company did not disclose the commercial terms of the sale.

Rhythm managing-director Dr David Atkins said although non-material, at present, the company was "confident that the suite of products will support commercial revenue growth over ensuing periods [and] with growing revenues expected from the Genetype product portfolio, we look forward to adding to this with Colostat commercial revenues in the next financial year".

Genetic Technologies previously said that Genetype was developed to provide risk assessments for breast cancer (BD: Dec 10, 2019).

Rhythm was up 0.1 cents or 1.1 percent to nine cents.

BLINKLAB

Blinklab says it will conduct a 200-adult patient study of its autism detection software with Netherlands' Vrije Universiteit Amsterdam and the Netherlands Autism Register.
Blinklab said the study would enrol 100 patients with autism and 100 patients without autism and would be the first to evaluate its autism detection application in adults and individuals with late-diagnosed autism, with a particular emphasis on autism in women.
The company said the study would test whether "objective neuro-metric evaluations" could assist diagnosing autism and would complement its US Food and Drug Administration registrational trial for its Dx1 smartphone-based application for diagnosing autism in children aged two-to-11 years old.
Blinklab said the Netherlands Autism Register was a database with about 6,800 patients established in 2013 by the Nederlandse Vereniging voor Autisme (NVA) in collaboration with Vrije Universiteit Amsterdam.
The company said the register conducted long-term research on autism by collecting data through surveys, cognitive assessments, electro-encephalography measurements and genetic screening.
Blinklab said data collection would begin in April, with results expected in August 2025.
The company said the study had "the potential to significantly expand our addressable market for autism diagnosis by showing that Blinklab Dx1 could be an effective platform for autism diagnosis across all age groups'.
Blinklab was up 4.5 cents or 11.4 percent to 44 cents.

BIOXYNE

Bioxyne has requested a trading halt pending an announcement to the market "concerning a capital raising".
Trading will resume on March 21, 2025, or on an earlier announcement.
Bioxyne last traded at three cents.

CAMBIUM BIO (FORMERLY REGENEUS)

Cambium says it has reduced its holding and been diluted in itself in a placement and share consolidation from 246,808,905 shares (20.7%) to 2,468,094 shares (13.5%).
Last year, Cambium said 96.64 percent of investors approved a 100-to-one stock consolidation, with 11,931,006 post-consolidation shares on issue (BD: Jul 12, 2024).
Later, the company said it raised $3.0 million at a post-consolidation 46.37 cents a share in a placement to fund phase III trials (BD: Dec 5, 2024).
Cambium was unchanged at 35 cents with one share traded.

IMRICOR MEDICAL SYSTEMS

Imricor has requested a suspension following Monday's trading halt pending an announcement "in relation to a proposed capital raising" (BD: Mar 17, 2025).
Trading will resume on March 20, 2025, or on an earlier announcement.
Imricor last traded at $1.41.

OPTHEA

Opthea has requested a suspension following Monday's trading halt "in relation to the top line results of its phase III 'Coast' clinical trial" (BD: Mar 17, 2025).
Trading will resume on March 24, 2025, or on an earlier announcement.
Opthea last traded at 60 cents.