Biotech Daily

Wednesday December 11, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: IMUGENE UP 8%; PARADIGM DOWN 14%**

*** NEXSEN DEVELOPS STREPSURE STREPTOCOCCUS TEST**

*** AMPLIA: '9 PARTIAL PANCREATIC CANCER RESPONSES TO AMP945'**

*** NEUORPHAN TO PAY OPYL $5k/REPORT FOR A.I. TRIAL DESIGNS**

*** ISLAND US ISLA-101 DENGUE FEVER PATENT**

*** EYE CO EU 'ALVIZON' FOR DRY AMD PATENT**

*** NEURIZON RECEIVES $651k FEDERAL R&D TAX INCENTIVE**

*** ENLITIC TO RELEASE 4.8m VOLUNTARY ESCROW SHARES**

*** JDB SERVICES, RAC & JD BRICE DILUTED TO 5.6% OF AUDEARA**

*** GILLIAN NAIRN REPLACES MEDADVISOR CO-CO SEC ANSHU RAGHUVANSHI**

*** SHELBY COLEMAN REPLACES LTR CO SEC BELINDA CLEMINSON**

MARKET REPORT

The Australian stock market fell 0.47 percent on Wednesday December 11, 2024, with the ASX200 down 39.4 points to 8,353.6 points. Eight of the Biotech Daily Top 40 companies were up, 24 fell, four traded unchanged and four were untraded.

Imugene was the best, up 0.3 cents or 7.9 percent to 4.1 cents, with 29.1 million shares traded. SDI climbed 6.1 percent; Immutep and Orthocell improved more than four percent; Amplia and Neuren were up more than three percent; Dimerix rose 2.7 percent; Percheron and Pro Medicus were up more than one percent; with Resmed up by 0.2 percent.

Paradigm led the falls, down seven cents or 13.6 percent to 44.5 cents, with 3.8 million shares traded. Curvebeam lost 7.1 percent; Atomo and Clarity were down five percent or more; Emvision, Medadvisor, Mesoblast, Prescient and Starpharma fell more than four percent; 4D Medical, Actinogen, Aroa, Avita, Impedimed, Micro-X, Nanosonics, Nova Eye, and Opthea were down three percent or more; EBR and Medical Developments shed more than two percent; Genetic Signatures, Polynovo and Telix were down by more than one percent; with Clinuvel, Cochlear and CSL down by less than one percent.

NEXSEN BIOTECH PTY LTD

Melbourne's Nexsen says it is developing its Strepsure "world's first, rapid diagnostic test for group B streptococcus" (GBS) infection.

Nexsen said for group B streptococcus was "a leading cause for neo-natal sepsis, meningitis, and pneumonia, which leads to significant mortality and morbidity in newborns globally".

The company said its Strepsure technology used "aptamer-based nano-diagnostic technology to achieve high-specificity and sensitivity in testing".

Nexsen said aptamers were synthetic DNA molecules that "bind selectively to specific biomarkers, minimizing false positives and enhancing test accuracy".

The company said that unlike traditional for group B streptococcus testing methods that took 18-to-24 hours, Strepsure delivered results "within 15-to-20 minutes, empowering clinicians to administer timely antibiotic treatment".

According to the Nexsen website, the hand-held device used a swab taken by a clinician or patient which was then inserted into the test, with results shown on the test.

Nexsen said "whilst its use will predominately be within clinical settings, its portability and intended 'over-the-counter' availability, will allow a test to be done at any time, and in any situation".

The website said Thomas Hanly was the company's managing-director, Mark Muzzin was its chair, with Martina Mariano and Gavin Ball non-executive directors and RMIT's Prof Vipul Bansal as its lead researcher and advisor.

Nexsen managing-director Thomas Hanly told Biotech Daily that the company was conducting a 3,000-patient sample trial at Northern Health's Epping Hospital, in Victoria's northern suburbs to validate Strepsure for regulatory submissions.

Mr Hanly said he expected the trial to be completed "by this time next year" with a US Food and Drug Administration 510(k) application expected to be lodged "in early 2026".

Mr Hanly said that following FDA submissions Nexsen would apply to the Australian Therapeutic Goods Administration, Health Canada and regulators in other jurisdictions.

Mr Hanly said that once approved, the company expected the test to cost about $2.00.

Nexsen said its tests were "easy to use, require minimal training, and eliminate the need for cold chain logistics".

The company said Strepsure was "designed for universal screening, particularly in remote and low-resource settings, where access to laboratory infrastructure is limited".

Nexsen said there were 2.9 million neo-natal deaths a year and that infections such as group B streptococcus remained "a significant threat to maternal and infant health".

The company said "up-to one-in-five pregnant women carry GBS, often unknowingly".

Nexsen said group B streptococcus contributed to complications such as pre-term births and stillbirths, particularly in low-income regions, where universal screening was unavailable.

Nexsen's website said the company had a $5 million, five-year funding deal with the Royal Melbourne Institute of Technology for the Strepsure research program and $1.75 million from the Federal Government for its veterinary tests.

The company said it was developing Vetstrep for testing bovine mastitis as well as a prostate specific antigen diagnostic for prostate cancer and a creatinine test for at-home kidney function testing.

In February, the Royal Melbourne Institute of Technology said that it had a $7.6 million partnership with Nexsen, Northern Health and Atomo Diagnostics to develop Strepsure, including a $3 million grant from the Federal Government for trials.

Nexsen is a private company.

AMPLIA THERAPEUTICS

Amplia says it has nine confirmed partial responses in its 26-patient, phase IIa trial of narmafotinib, formerly AMP945, with standard-of-care for pancreatic cancer.

In September, Amplia said six of 26 enrolled patients in its 50-patient, phase IIa, trial of AMP945 for pancreatic cancer showed reduced tumor size with no new lesions, allowing it to begin recruitment of the remaining 24 patients (BD: Sep 23, 2024).

In October, the company said 15 of the 26 patients enrolled in the first part of its 50-patient, phase IIa trial "remain on trial" (BD: Oct 30, 2024).

Today, Amplia said 11 of the initial 26 patients remained on trial with narmafotinib continuing "to be generally well tolerated by patients and no patients have withdrawn from study due to issues from narmafotinib".

The company said that nine of 26 partial responders was a 34.6 percent objective response rate "significantly better than the 23 percent reported for the historical trial being used as the benchmark for this study".

Amplia said that a confirmed partial response was recorded when there was "at least a 30 percent decrease in the overall size of tumor lesions sustained for two or more months, with no new tumor lesions apparent".

The company said that the median duration on trial for the 26 patients was 172 days, "a 47 percent improvement over the historical data of 117 days", with duration on trial a measure of how effective the treatment was in inhibiting disease progression.

Amplia said it had enrolled 12 patients since re-opening recruitment in October.

Amplia managing-director Dr Chris Burns said that adding narmafotinib to the standard-of-care treatment continued "to show promise in comparison to the historical data for standard-of-care alone".

"We've recruited over 75 percent of the trial at this time, and with ongoing positive support from clinicians involved in the study, we are well on track to fully recruit the trial by end of [March] 2025," Dr Burns said.

"In addition, we have been reassured by our clinical team in [South] Korea that the recent political situation in the country is not impacting the trial sites located there in terms of recruitment and ongoing support of patients," Dr Burns said.

Multiple news outlets last week reported that South Korea's President Yoon Suk Yeol declared martial law, which was later lifted following a National Assembly vote.

Amplia was up 0.3 cents or 3.5 percent to 8.9 cents with 14.8 million shares traded.

OPYL

Opyl says Melbourne's Neuorphan Pty Ltd will use its Trialkey artificial intelligence (A.I.)-based service for analyzing clinical trials for $5,000 per report.

Earlier this year, Opyl said clinical research organization Biointelect would use Trialkey for $5,000 per trial (BD: Sep 25, 2024).

Today, the company said it Neuorphan was developing Dioprotectome, a therapy for multiple sclerosis and other neurological disorders that aimed to "protect the central nervous system from inflammatory damage and promoted repair".

Opyl said Trialkey would provide Neuorphan with reports to support the development of Neuorphan's therapies, but did not state the number of reports it expected to provide.

Opyl executive chair Saurabh Jain said Trialkey was "not just a platform; it's a game-changer for clinical trials".

"Neuorphan's decision to deepen this partnership is a testament to the unmatched quality and impact of our insights," Mr Jain said.

Opyl fell 0.2 cents or 6.25 percent to three cents with 1.6 million shares traded.

ISLAND PHARMACEUTICALS

Island says the US Patent and Trademark Office has granted it a patent for ISLA-101 as a "method of reducing the severity of one or more symptoms of dengue virus".
Island said the patent, titled 'Method of viral inhibition' would protect its intellectual property until April 16, 2034.
The company said it licenced the intellectual property for ISLA-101, developed by Melbourne's Monash University, and the latest patent added to its intellectual property portfolio that included Australia, Canada, Brazil and Singapore.
Island managing-director Dr David Foster said the company was "pleased to have been awarded this latest US patent, which bolsters our expanding intellectual property portfolio and provides enhanced protection for our flagship program, ISLA-101".
"As we continue to advance our phase IIa/b ISLA-101 clinical trial, our [intellectual property] program remains fundamental to its success," Dr Foster said.
Island was up two cents or 13.3 percent to 17 cents.

EYE CO PTY LTD

Eye Co says the European Patent Office has granted it a patent relating to its lead compound fludrocortisone acetate, branded as Alvizon.
Eye Co said the patent, titled 'Composition and method of treatment for Dry AMD (Age Related Macular Degeneration)' would protect its intellectual property until 2039.
The company said the patent recognized the ability of fludrocortisone acetate to modulate the activity of both the gluco-corticoid and mineralo-corticoid receptors in the retina, meaning that unlike other steroids it provided "a balance of suppressing inflammation and improving retinal function".
Eye Co said that the patent included the use of Alvizon as a prophylactic treatment.
The company said it had begun the first stage of an in-human study of Alvizon for the treatment of late stage dry age-related macular degeneration.
Eye Co is a private company.

NEURIZON (FORMERLY PHARMAUST)

Neurizon says it has received $650,707 from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.
Neurizon said the incentive related to an Ausindustry advanced overseas finding application for research and development expenditure for the year to June 30, 2024 and was in addition to the $887,129 incentive received earlier this year (BD: Oct 9, 2024).
Neurizon was up half a cent or 2.9 percent to 17.5 cents.

ENLITIC

Enlitic says it will release 4,782,172 Chess depository interests (CDIs) from voluntary escrow on December 18, 2024.
According to its most recent filing, Enlitic had 575,584,310 CDIs, equal to one US share, available for trading and 7,558,404 restricted common stock (US shares).
The company told Biotech Daily that the securities were to be released from voluntary escrow and were part of the 575,584,310 CDIs listed for trading on the ASX.
Enlitic was up 0.4 cents or 5.9 percent to 7.2 cents.

AUDEARA

Brisbane's JDB Services Pty Ltd and RAC & JD Brice Invest say their 9,713,777 share-holding in Audeara has been diluted from 6.78 percent to 5.56 percent.
Last week, Audeara said it had commitments to raise $1.35 million at four cents a share, with one attaching option for every three shares issued (BD: Dec 5, 2024).
Audeara was unchanged at 4.4 cents.

MEDADVISOR

Medadvisor says it has appointed Gillian Nairn as co-company secretary, effective today, following the resignation of Anshu Raghuvanshi "to pursue new opportunities".
Medadvisor said that Ancila Desai continues as chief financial officer and company secretary.
Medadvisor fell 1.5 cents or 4.8 percent to 30 cents.

LTR PHARMA

LTR says it has appointed Automic Group's Shelby Coleman as its company secretary, effective immediately, following Belinda Cleminson's resignation from Automic.
LTR fell five cents or 5.1 percent to 93 cents.