Biotech Daily

Monday March 17, 2025

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ORTHOCELL UP 10.5%; ATOMO DOWN 10.5%**

*** GARVAN: 'NPY POTENTIAL PANCREATIC CANCER TARGET'**

*** TRIVARX RAISES $2m**

*** FEDERAL $500k FOR FIVEPHUSION, WOLLONGONG UNI RESECTASSIST**

*** UNIVERSAL BIOSENSORS SALES 'SLOWER THAN EXPECTED'**

*** RADIOPHARM RAD202 'SAFE, PROLONGS SURVIVAL, IN MICE'**

*** ARGENT PHASE IIb CIMETRA COVID TRIAL: 'SAFE, WELL TOLERATED'**

*** NEURIZON ASKS FDA ADVICE ON NUZ-001 CLINICAL HOLD STUDIES**

*** NYRADA BEGINS NYR-BI03 PHASE I TRIAL RECRUITMENT**

*** OPTHEA REQUESTS 'TRIAL RESULTS' TRADING HALT**

*** IMRICOR REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** RESPIRI 'VITASORA' NAME CHANGE EGM**

*** INOVIQ APPOINTS DR EMMA BALL CCO**

MARKET REPORT

The Australian stock market rose 0.83 percent on Monday March 17, 2025, with the ASX200 up 64.4 points to 7,854.1 points. Nineteen Biotech Daily Top 40 stocks were up, 12 fell, seven traded unchanged and two were untraded. The four Big Caps were mixed.

Orthocell was the best, up 13 cents or 10.5 percent to $1.37, with 1.8 million shares traded. Actinogen was up 6.7 percent; Curvebeam climbed 4.8 percent Neuren was up 3.25 percent; Alcidion, Aroa, Dimerix, EBR, Polynovo, Prescient and Proteomics rose two percent or more; Paradigm and Syntara were up more than one percent; with Avita, Clinuvel, Cochlear, Mesoblast, Nanosonics, Pro Medicus, SDI and Telix up by less than one percent.

Atomo led the falls, down 0.2 cents or 10.5 percent to 1.7 cents, with 913,853 shares traded. Percheron lost 9.1 percent; Medadvisor shed 8.3 percent; Genetic Signatures fell 5.4 percent; Medical Developments was down 4.55 percent; Clarity, Cynata and Micro-X were down more than three percent; Cyclopharm and Imugene shed more than two percent; 4D Medical, Emvision and Resmed were down more than one percent; with CSL down by 0.9 percent.

THE GARVAN INSTITUTE OF MEDICAL RESEARCH

The Garvan Institute says the neuropeptide Y (NPY) molecule is linked to pancreatic cancer metastasis and it is studying an anti-body to block the molecule, in mice.

The Garvan said researchers found that by blocking the NPY molecule in mouse models they could "substantially reduce the spread of pancreatic cancer to the liver, the most common site of metastasis in patients".

The Institute said the study was "the first time the role of NPY has been investigated in pancreatic cancer metastasis, building on previous research that linked the molecule to cancer progression in breast, prostate and neuro-blastoma cancers".

The Garvan said the study, titled 'Targeting the NPY/NPY1R signaling axis in mutant p53–dependent pancreatic cancer impairs metastasis' was published in Science Advances and available at: https://www.science.org/doi/10.1126/sciadv.adq4416.

The Institute said researchers found high levels of NPY in aggressive and metastatic pancreatic cancers and suggested "that blocking NPY could be an effective personalized treatment for this subset of patients, as well as those who experience severe weight loss due to cancer".

The Garvan said that in addition to the anti-metastatic effect, blocking NPY "helped reduce the loss of muscle and fat tissue mass, known as cachexia, that often accompanies cancer progression".

The Institute said the additional benefit to maintain muscle and fat tissue "could be crucial for patients to tolerate chemotherapy and other treatments".

The Garvan Institute said it had developed an antibody designed to neutralize NPY's effect in cancer which it was currently testing in mice and in tissue donated by pancreatic cancer patients.

The Garvan said the study provided preliminary evidence that inhibiting NPY might reduce cancer spread and reduce weight loss and it was working to optimize how this strategy could be combined with existing treatments to be taken to clinical trials.

Garvan study lead Dr David Herrmann said NPY was "a signaling molecule best known for its role in regulating metabolism, appetite and satiety".

"These preliminary findings reveal this molecule as a promising target to investigate further for pancreatic cancer," Dr Herrmann said.

"One of our next steps is to refine how we use this approach in combination with chemotherapy," Dr Herrmann said.

TRIVARX (FORMERLY MEDIBIO)

Trivarx says it has "firm commitments" to raise $2.25 million at 1.5 cents a share in an institutional placement with one attaching option for every two shares received.

Trivarx said that the placement issue price was a 9.52 percent discount to the 15-day volume weighted average price and was equal to its last traded price of 1.5 cents on March 11, 2025.

The company said funds would be used for its 60-patient trial of its screening algorithm for major depressive episodes with the US Department of Veterans Affairs and Greater Los Angeles Veterans Research and Education Foundation (BD: Mar 13, 2025).

Trivarx said that the options would be exercisable at 2.5 cents each, within 36 months from issue.

The company said Perth's JP Equity Partners was lead manager and would receive a six percent capital raising fee, as well as 9,000,000 options, subject to shareholder approval.

Trivarx was up 0.2 cents or 13.3 percent to 1.7 cents with 5.8 million shares traded.

FIVEPHUSION, THE UNIVERSITY OF WOLLONGONG

Fivephusion says the Federal Government has granted $500,000 for the development of the Resectassist implantable, drug-eluting device for pancreatic cancer.
Last year, Fivephusion said it had an “exclusive option” to develop the University of Wollongong’s single-use, drug-eluting, bio-degradable Resectassist implantable drug delivery system for solid tumors (BD: Dec 9, 2024).
At that time, the company said Resectassit allowed for the “targeted administration of a diverse range of approved and investigational drugs directly into solid tumors”
Today, Fivephusion said the University of Wollongong and the University of South Australia had received the maximum funding available under the Federal Government’s Australian Economic Accelerate Ignite grants program, which supported “nationally significant research and commercialization projects”.
The company said the funds would allow it to continue to work with the University of Wollongong in “developing a device that will target inoperable pancreatic tumors”.
The University of Wollongong’s Prof Kara Vine-Perrow said the cancer drug-eluting device would “minimize systemic side effects and maximize treatment efficacy, potentially transforming treatment and care for cancer patients”.
Fivephusion is a private company.

UNIVERSAL BIOSENSORS

Universal Biosensors says adoption of its devices has been “slower than expected” with sales of Xprecia and Sentia tests “below market expectations”.
An announcement, titled ‘Chairman’s Letter’ from Universal Biosensors chair Graham McLean, said that adoption of its devices, including its Xprecia Prime blood coagulation test and Sentia wine-testing device was slow due to “entrenched customer habits, limited awareness, regulatory delays and competitive market environments”.
The company said it was “confident the prospects for the future are brighter than ever”.
Universal Biosensors said that last year it had received US Food and Drug Administration 510k clearance for Xprecia Prime, expanded its US sales team, signed two distribution agreements distribution, received its first shipment of Xprecia Prime devices and recorded first sales (BD: Mar 19, Nov 19, 2024).
The company said Xprecia Prime’s adoption for point-of-care testing in the US depended on “middleware integration for seamless communication with hospital and clinic patient record systems” and that validating these platforms had taken time.
Universal Biosensors said that “one of the largest platforms is expected to go live within the next month, removing the last barrier to widespread adoption in major US clinics and medical institutions”.
The company said that “no other product replicates Sentia’s on-the-spot testing” and the wine test had been adopted by nine percent of US wineries, 25 percent of Australian wineries, 17 percent of Canadian wineries and nine percent of New Zealand wineries.
Universal Biosensors said it had addressed performance issues with Sentia’s free sulfur dioxide test strips which impacted sales in the six months to June 30, 2024 and “demand rebounded … with record test strip sales” in the three months to September 30, 2024.
Universal Biosensors said Europe, “the world’s largest wine market, remains more cautious and reliant on more traditional methods compared to their counterparts in the ‘new world’ regions, leading to a slower adoption curve for new technologies”.
The company said it intended to implement efficiency initiatives in 2025 and had “eliminated $1.1 million of annual costs and expect to reduce costs by another $1 million”.
Universal Biosensors was unchanged at 7.2 cents.

RADIOPHARM THERANOSTICS

Radiopharm says it has presented data supporting the use of its gallium-68 RAD202 diagnostic and lutetium-177 RAD202 radio-therapy for pancreatic cancer, in mice.
Last year, Radiopharm said that gallium-68 RAD202 had led to a “rapid tumor uptake and high tumor-to-background ratio” as a therapy and as an imaging agent for tumors, in mice (BD: Oct 23, 2024).
At the time, the company said RAD202 was a nanobody targeting the human epidermal growth factor receptor 2, or HER2, which was overexpressed in breast cancer and other solid tumors.
In December, Radiopharm said it had ethics approval to begin a phase I trial of lutetium-177 RAD202 for treating HER2-expressing solid tumors (BD: Dec 20, 2024).
Today, the company said data showed gallium-68 RAD202 for imaging, bound specifically to HER2 in HER2-positive xenografts.
Radiopharm said removing the polyhistidine-tag from RAD202, a modification which impacted bio-distribution and tumor targeting, was shown to be superior for positron emission tomography imaging due to the higher tumor-to-organ ratio.
The company said therapy with lutetium-177 RAD202 was well-tolerated, showed “significantly prolonged survival time” and that the fractionated dose was more effective in inhibiting tumor growth compared to single-dose therapy.
Radiopharm said the data was presented at the European Molecular Imaging meeting, held from March 11 to 14, 2025 in Bilbao, Spain.
Radiopharm managing-director Riccardo Canevari said the data supported the potential for RAD202 “to address an unmet need for HER2-positive metastatic patients that are progressing on current standard-of-care, or unable to tolerate current treatment options”.
Radiopharm was up 0.3 cents or 10.7 percent to 3.1 cents with 13.8 million shares traded.

ARGENT BIOPHARMA (FORMERLY MGC PHARMACEUTICALS)

Argent says its 29-patient, phase IIb trial of Cimetra showed a “strong safety profile with no drug-related adverse events”.
In 2020, the then MGC said a 50-patient, phase II trial of the then Artemic, now Cimetra, for Covid-19 patients in Israel and India had “met the primary and secondary endpoints” (BD: Dec 15, 2020).
In 2021, the company said it had ethics approval from two Israeli hospitals to begin a 252-patient, phase III trial of Cimetra for Covid-19 patients (BD: Mar 23, 2021).
Today, Argent said Cimetra was composed of Curcuma longa (turmeric) and Boswellia serrata (Indian frankincense).
The company said patients in the phase IIb, double-blind, randomized, placebo-controlled trial of Cimetra for COVID-19 showed “a positive trend toward faster recover and symptom improvement compared to placebo”, including “promising modulation” of inflammatory marker interleukin 6 (IL-6).
Argent did not discuss statistical significance.
Biotech Daily could not find a reference to the beginning of a phase IIb trial, nor the end of the phase III trial.
Argent said additional, larger-scale trials were required to further validate Cimetra’s efficacy and that based on the positive findings it would advance regulatory discussions and continue to engage potential commercial partners.
Argent fell half a cent or 3.85 percent to a post-1000-to-one consolidation 12.5 cents with 25 (twenty-five) shares traded.

NEURIZON THERAPEUTICS (FORMERLY PHARMAUST)

Neurizon says it has requested advice on two “short-term, low-cost” studies with the US Food and Drug Administration to lift the clinical hold on NUZ-001.

Last year, the-then Pharmaust said the FDA requested further data for its monepantel orphan drug designation application for motor neuron disease (MND) “due to the absence of pre-clinical or clinical data to establish the potential for the drug to be effective in MND [and, or amyotrophic lateral sclerosis]” (BD: Jan 29, 2024).

Earlier this year, Neurizon said the FDA put its investigational new drug application for NUZ-001, formerly monepantel, for amyotrophic lateral sclerosis (ALS), or motor neuron disease, on a “clinical hold” (BD: Jan 19, 2025).

At that time, the company said the clinical hold followed “certain concerns about the sufficiency of information to assess the application and any risks to human subjects of the trial and with the proposed dosing regime”.

In February, Neurizon said the FDA had requested “additional animal exposure data to assess the adequacy of systemic exposure to NUZ-001” (BD: Feb 17, 2025).

Today, the company said it had submitted a formal request “for advice detailing two short-term, low-cost pharmacokinetic studies necessary to lift the clinical hold”.

Neurizon said it expected to begin the studies in the coming weeks, they would take about four months and were expected to cost between $400,000 and $600,000.

Neurizon said the decision to “proactively undertake the additional studies prior to the pending formal response from the FDA follows extensive engagement between the board, management and the company’s scientific and regulatory advisors”.

The company said the additional pharmaco-kinetic data from the studies would “support ongoing clinical development of NUZ-001 and future regulatory approval applications”.

Neurizon managing-director Dr Michael Thurn said undertaking the studies prior to the receipt of a formal response from the FDA showed “the company’s proactive approach to satisfying the regulator’s request and our ongoing commitment to advancing NUZ-001 as an effective potential treatment for ALS and other neuro-degenerative diseases”.

“The timely execution of these studies will allow NUZ-001 entry into the ‘Healey’ ALS platform trial during the second half of 2025,” Dr Thurn said.

Last year, the then Pharmaust said Massachusetts General Hospital had accepted the then monepantel, now NUZ-001, into its phase II/III ‘Healey’ amyotrophic lateral sclerosis, or motor neuron disease platform trial (BD: Jul 15, 2024).

Later, the company said it has filed an investigational new drug application to the FDA to conduct a phase II/III trial of NUZ-001 for ALS “within the ‘Healey’ ALS platform trial framework” (BD: Dec 18, 2024).

Neurizon fell one cent or 9.1 percent to 10 cents with 1.4 million shares traded.

NYRADA

Nyrada says it has begun recruiting its 40-patient, phase I trial of NYR-BI03 for traumatic brain injury and stroke, with dosing expected to begin this month.

Last year, Nyrada said it had completed pre-clinical studies and expected the phase I trial of intra-venous NYR-BI03 to begin in 2024; and last month, said it had human research ethics approval to begin the trial (BD: Oct 16, 2024; Feb 7, 2025).

Today, the company said the trial would assess safety, tolerability and pharmacokinetics, with results expected by October 2025.

Nyrada said the trial was being conducted at Sydney’s Scientia Clinical Research and Southern Star Research was the contract research organization.

Nyrada was up half a cent or five percent to 10.5 cents.

OPTHEA

Opthea has requested a trading halt pending an announcement “in relation to the top line results of its phase III ‘Coast’ clinical trial”.
In 2021, Opthea said it had treated the first of about 1,980 patients in the US and Canada, for its two randomized, double-blind, controlled trials, evaluating the efficacy and safety of OPT-302 for wet AMD in combination with either ranibizumab (Shore) or aflibercept, (Coast) compared to ranibizumab or aflibercept alone (BD: Mar 15, 2021).
Trading will resume on March 19, 2025, or on an earlier announcement.
Opthea last traded at 60 cents.

IMRICOR MEDICAL SYSTEMS INC

Imricor has requested a trading halt “pending an announcement to be made by the company to the market in relation to a proposed capital raising”.
Trading will resume on March 19, 2025, or on an earlier announcement.
Imricor last traded at $1.41.

RESPIRI (FORMERLY ISONEA, KARMELSONIX)

Respiri says its extraordinary general meeting will vote to change its name to ‘Vitasora Health Ltd’, with its ASX ticker code to become ‘VHL’.
Earlier this month, Respiri said it would change its name to ‘Vitasora Health Ltd’, had reserved ‘VHL’ as its proposed ASX ticker code and had “firm commitments” to raise $4.0 million at 4.0 cents a share in a placement (BD: Mar 3, 2025).
The company said ‘vita’ was Latin for ‘life’, ‘sora’ was Japanese for ‘sky’ and Vitasora reflected its commitment to patient-centric care, improving and sustaining health and to enhance patient outcomes, reduce costs, and drive value-based care beyond the clinic.
In 2011, the then Karmelsonix changed its name to Isonea, and in December 2015 changed its name to Respiri (BD: Aug 30, 2011).
Today, the company said the meeting would vote to ratify the prior issue of placement shares and issue the second tranche of placement shares.
The meeting will be held online on April 16, 2025 at 11am (AEDT).
Respiri fell 0.1 cents or 2.4 percent to four cents with 2.7 million shares traded.

INOVIQ

Inoviq says it has appointed Dr Emma Ball as its chief commercial officer, effective from April 22, 2025.
Inoviq said Dr Ball had more than 25 years of experience, was non-executive chair of the Bio-Melbourne Network and had been head of ecosystem development at Illumina Inc and worked at CSL for 15 years in various roles.
The company said Dr Ball held a Bachelor of Science and a Doctor of Philosophy from the University of Melbourne as well as a Master of Business Administration from the Royal Melbourne Institute of Technology, and earlier this month Dr Ball was appointed chair of the Bio-Melbourne Network (BD: Mar 6, 2025)
Inoviq was up 1.5 cents or 4.2 percent to 37 cents.