Biotech Daily

Monday February 17, 2025

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: 4D MEDICAL UP 9%; EMVISION DOWN 11%**

*** SNOW $50m FOR SYDNEY UNI GLAUCOMA RESEARCH**

*** PYC UP-TO $146m RIGHTS OFFER; TRADING HALT**

*** RECCE: 'R327 MEETS SKIN INFECTION TRIAL PRIMARY ENDPOINT'**

*** QBIOTICS: 'TIGILANOL TIGLATE SHOWS RAPID SYSTEMIC CLEARANCE'**

*** AXELIA PHASE I AXA-042, LIBTAYO SOLID TUMORS TRIAL**

*** OSTEOPORE TAKES $2m OF ADVANCE OPPORTUNITIES $20m NOTE**

*** MEMPHASYS, ANDROSCIENCE BRAZIL FELIX IVF STUDY**

*** NEURIZON: FDA REQUESTS MORE NUZ-001 ANIMAL DATA**

*** AUSBIOTECH 1st WOMEN IN LIFE SCIENCES LEADERSHIP SUMMIT**

MARKET REPORT

The Australian stock market fell 0.22 percent on Monday February 17, 2025, with the ASX200 down 18.7 points to 8,537.1 points. Eighteen of the Biotech Daily Top 40 companies were up, 13 fell, eight traded unchanged and one was untraded. The four Big Caps were mixed.

4D Medical was the best, up 4.5 cents or nine percent to 54.5 cents, with 502,523 shares traded. Avita and Paradigm were up more than eight percent; Cochlear and Prescient climbed more than four percent; Clarity, Immutep, Medadvisor, Nova Eye, Orthocell and Polynovo were up three percent or more; Aroa rose 2.7 percent; Amplia, Mesoblast, Nanosonics, Neuren and Telix were up more than one percent; with CSL, EBR and Opthea up by less than one percent.

Emvision led the falls, down 22 cents or 10.6 percent to $1.86, with 87,244 shares traded. Medical Developments lost five percent; Imugene, Resonance and SDI fell more than four percent; Actinogen, Cynata, Dimerix, Impedimed, Micro-X and Resmed shed two percent or more; Cyclopharm and Genetic Signatures were down one percent or more; with Clinuvel and Pro Medicus down by less than one percent.

SNOW MEDICAL RESEARCH FOUNDATION

The Snow Medical Research Foundation says it will invest $5 million a year for 10 years to open a glaucoma research accelerator with the University of Sydney.

A Snow Medical media release said that with the University of Sydney it would open its Snow Vision Accelerator “to fight glaucoma, the world’s leading cause of irreversible blindness”.

The Foundation said the accelerator would be led by University of Sydney ophthalmologist Prof Jonathan Crowston and located at the University’s Charles Perkins Centre.

The University said the Snow Vision Accelerator would build on the work of Prof Jonathan Crowston to develop treatments that enhanced the ability of optic nerve cells to withstand injury and survive, addressing an unmet need for effective therapies.

Snow Medical said the accelerator would bring together Australian and international researchers and support a team of scientists based at the University of Sydney.

The Foundation said the partnership was expected to employ more than 40 scientists, clinicians and staff within five years, with operations expected to begin in mid-2025.

Snow Medical said the accelerator would combine “high-risk, high-reward science, the University of Sydney's capacity, and long-term Snow family investment to create transformative health and medical outcomes for patients”.

The Foundation said the partnership would accelerate translation and impact “by putting in place structures to support impact-focused research teams and accelerate transformation in glaucoma therapy … [and would embrace] flexibility and change, with the science leading the direction, fostering a multi-disciplinary, entrepreneurial environment that values calculated risk and bold solutions”.

Snow Medical said the research would honor the legacy of the late Terry Snow by operating quickly and actively working to remove barriers to research and its translation.

In 2023, the Walter and Eliza Hall Institute said the Snow Foundation would invest $10 million a year for 10-years to open an immunology research centre with the Royal Melbourne Hospital (BD: Nov 20, 2023).

A separate media release from the University of Sydney said the funding was “the largest single philanthropic investment in vision science in Australia”.

The University said glaucoma affected “80 million people globally, with 4.5 million completely blind in both eyes”.

The University of Sydney said the disease was often referred to as the ‘sneak thief of sight’ because it progressed silently until significant vision was lost and that current treatments focused “solely on lowering eye pressure, leaving age-related vulnerabilities and optic nerve resilience largely unaddressed”.

The University said that in addition to advancing drug development, the program aimed “to build Australia's reputation as a global leader in eye research and to attract additional funding from government, philanthropy, and the private sector”.

The University of Sydney said that it had a collaboration with Monash Institute of Pharmaceutical Sciences that would strengthen the translation of discoveries at the Snow Vision Accelerator into clinical applications.

The Foundation said the accelerator would be supported by an advisory committee led by Lions Eye Institute founder and director Prof Ioan Constable, with members including WEHI’s Prof Melanie Bahlo and the University of New South Wales’ Prof Nigel Turner.

Snow Medical chair Tom Snow said the investment was “designed in partnership with the University of Sydney to revolutionize how we treat glaucoma and prevent blindness for millions of people worldwide”.

“Our family backs high-risk, high-reward science that addresses the most pressing global health challenges,” Mr Snow said.

PYC THERAPEUTICS

PYC says it hopes to raise up-to $146 million at $1.25 a share in an underwritten, one-for-four, non-renounceable institutional and retail entitlement offer.
PYC said the issue price was a 4.9 percent discount to the five-day volume weighted average price and a 2.7 percent discount to the last traded price.
The company said the rights offer was underwritten up-to $70 million by shareholders Custom Binders, John Baird, Sami Zouad, Adrian Bonaddio and the Papy Family Trust.
PYC said chair Alan Tribe's Australian Land Pty Ltd, which owned 34 percent of its issued capital, had subscribed for $35 million under the offer.
The company said the funds would be used for late-stage human trials of its first eye disease drug, mid-stage human trials for its second eye disease drug candidate and early-stage trials for its polycystic kidney disease drug candidate.
PYC said it would use the proceeds to progress its Phelan-McDermid syndrome drug program into human trials, further drug discovery and platform development efforts as well as general working capital.
The company said the retail offer had a record date of February 19, would open on February 24 and close March 14, 2025.
PYC said E&P Capital and Barrenjoey Markets were joint lead managers to the raise.
Separately, the company requested a trading halt "pending an announcement to the market regarding a proposed capital raising"
Trading will resume on February 19, 2025, or on an earlier announcement.
PYC last traded at $1.285.

RECCE PHARMACEUTICALS

Recce says its phase II study of R327 gel for acute bacterial skin and skin structure infections showed primary efficacy in 25 of 29 patients and has met all endpoints.
Last month, Recce said it had dosed all 30 patients in its phase II clinical trial of R327 topical gel for acute bacterial skin and skin structure infections (BD: Jan 21, 2025).
Today, the company said that at seven days, 25 patients (86.2%) had a clinical response and at 14 days, 27 patients (93.1%) achieved the primary efficacy endpoint.
Recce said R327 gel was "safe and well-tolerated", with no serious adverse events.
The company said it had enrolled 30 patients for the 14-day study, including men and women 18 years and older, but one patient withdrew due to pre-existing pain at the wound site unrelated to R327 gel.
Recce said acute bacterial skin and skin structure infections were a "significant healthcare concern", and included diabetic foot infections, necrotizing fasciitis, and post-operative wound infections.
The company said investigators rated patients cured or improved, with cured meaning a full clinical response and improved demonstrating partial wound healing with the potential of a cure beyond the 14-day timeline.
Recce said there were no placebo-controlled studies in acute bacterial skin and skin structure infection as international regulators deemed it unethical to withhold appropriate treatment of patient infections.
Recce chief executive officer James Graham said as the company advanced "towards registrational phase III trials in Indonesia, and Australia, we are encouraged by the rapid efficacy and strong safety outcomes demonstrated in this study".
"Going forward with our clinical programs, this gives us great confidence in addressing [acute bacterial skin and skin structure infections]," Mr Graham said.
Recce was unchanged at 45 cents.

QBIOTICS

Qbiotics says further data from its phase IIa trial of 11 soft tissue sarcoma patients shows tigilanol tiglate had “rapid systemic clearance after intra-tumoral injection”.

Last year, Qbiotics said its 11-patient, open-label, single-arm, phase IIa trial of intra-tumoral tigilanol tiglate for soft tissue sarcoma showed it exceeded “the primary endpoint for a promising response” and was safe (BD: Sep 17, Nov 19, 2024).

Today, the company said pharmaco-kinetic data showed tigilanol tiglate had a mean half-life of two hours.

Qbiotics said “measurable concentrations of tigilanol tiglate were observed in all patients from five minutes to four hours after dosing, with four patients having small but observable concentrations 24 hours after dosing.

The company said given its short half-life “more frequent dosing of tigilanol tiglate is to be explored in the trial expansion cohort, which is opening for enrolment shortly”.

Qbiotics said the data was presented in a poster, titled ‘Pharmacokinetics of intra-tumoral tigilanol tiglate in soft tissue sarcoma: data from a phase IIa clinical trial’ at the Society of Surgical Oncology’s Advanced Cancer Therapies, held in Phoenix, Arizona from February 14 to 17, 2025.

Qbiotics chief executive officer Stephen Doyle said pharmaco-kinetics was “essential for optimizing the use of tigilanol tiglate in treating patients”.

“We look forward to exploring the potential benefits of more frequent dosing in the upcoming trial expansion, which we expect to commence in the current quarter,” Mr Doyle said.

Qbiotics is a public unlisted company.

AXELIA ONCOLOGY PTY LTD

Axelia Oncology says it will conduct a phase I trial of its AXA-042 immune modulator with New York-based Regeneron’s Libtayo, or cemiplimab, for a range of solid tumors.

A Brandon Capital media release said Axelia had a supply agreement with Regeneron for a study of its AXA-042, an innate immune modulator targeting toll-like-receptors 2/6 (TLR2/6), in combination with Regeneron’s programmed death ligand-1 inhibitor Libtayo.

Axelia said the trial would study the safety and tolerability of AXA-042, a systemically-delivered agonist targeting TLR2/6, both as a mono-therapy and in combination with Libtayo across a range of solid tumors.

The company said it would “sponsor and be responsible for the conduct of the clinical study, which will be initiated at six clinical trial sites in Australia”.

Axelia said it was founded with investments from Brandon Capital’s Medical Research Commercialisation Fund and Uniseed, its chief executive officer was Dr Phil Kearney and its chief scientific officer was Dr Anna Galkin.

Axelia said AXA-042 was based on vaccine adjuvant research by the University of Melbourne’s Prof David Jackson and the Peter Doherty Institute.

Dr Kearney said that in pre-clinical studies “AXA-042 efficacy was macrophage-dependent and demonstrated enhanced activity in combination with checkpoint inhibitors”.

“These data provide a strong rationale for use of AXA-042 in cancer types unresponsive to anti-PD-1 due to myeloid cell mediated immune suppression,” Dr Kearney said.

“The monotherapy arm of the phase I trial has shown strong target engagement and impact on disease course in some patients, suggesting additional benefit may accrue with Libtayo,” Dr Kearney said.

Axelia is a private company.

OSTEOPORE

Osteopore says the Cayman Island's Advance Opportunities Fund has subscribed for $2.0 million worth of its $20 million redeemable convertible note agreement.

Last year, Osteopore said it expected to raise $20 million from Advance Opportunities for a redeemable convertible note at four percent a year, issuing in four equal tranches of 20 equal sub-tranches of $250,000 each (BD: Sep 27, 2024).

The company said at that time that the note had a conversion price at 80 percent of the average closing price on "any five consecutive business days" as selected by the noteholder during the 45 business days immediately preceding the conversion date.

Later, Osteopore said it had shareholder approval to issue up-to $20 million in convertible notes to Advance Opportunities Fund (BD: Jan 19, 2025).

Today, Osteopore said that the "conditions precedent" in the subscription agreement with respect of the first $5,000,000 tranche had been fulfilled and that Advance Opportunities had subscribed for eight equal sub-tranches, worth $2,000,000.

The company said the funds raised would be used for the "ordinary course of business and/or future developments, projects and investments as and when business opportunities arise, and for the discharge and/or reduction in loans".

Osteopore said it had agreed to use a portion of the funds to offset the repayment of the outstanding amount under its Advance Opportunities Fund loan agreement, and that "all indebtedness and obligations of the company in respect of the loan have been repaid and satisfied in full".

Last year, the company said it had extended its $S1,000,000 ($A1,170,000) loan from Advance Opportunities Fund from March 28, 2024 to May 1, 2025, at up-to eight percent monthly interest, to fund working capital requirements (BD: Apr 11, 2024).

Osteopore fell 0.2 cents or 6.45 percent to 2.9 cents, with three million shares traded.

MEMPHASYS

Memphasys says it will test its Felix sperm separation device for in-vitro fertilization (IVF) at Laboratorio Androscience, starting with 20 cartridges over three months.

Memphasys said that the Sao Paulo, Brazil-based Laboratorio Androscience's Prof Jorge Hallak would conduct a small trial and publish findings "to support market awareness and clinician engagement" following initial clinical testing of the device for IVF.

The company said the laboratory would test Felix against existing sperm preparation processes, including clinician training and a "small-scale" trial on men presenting with male infertility, which, if successful, could lead to a potential licencing deal for Brazil.

Memphasys said the results would be presented at a "major Brazilian reproductive medicine conference" in 2025, at which Memphasys would have a commercial booth to engage with local clinicians.

The company said that "sophisticated investors associated with Laboratorio Androscience" had expressed interest in supporting its activities in Brazil and "at this time no proposal has been received and there is no certainty of a proposal being received".

Memphasys chief executive officer David Ali said entering the Brazilian and potentially Latin American markets was "a significant commercial opportunity for Memphasys".

"The strong interest from both leading andrology and IVF clinicians and investors highlights the potential of the Felix system to improve male fertility evaluation, improving the search for the best sperm and reproductive outcomes," Mr Ali said.

Memphasys was unchanged at 0.8 cents with 1.6 million shares traded.

NEURIZON THERAPEUTICS (FORMERLY PHARMAUST)

Neurizon says the US Food and Drug Administration has requested “additional animal exposure data to assess the adequacy of systemic exposure to NUZ-001”.

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 “clinical hold” (BD: Jan 19, 2025).

At that time, the company said the 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”.

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).

Today, Neurizon said it had begun “initiatives to generate the additional exposure data and remains confident that further information will assist in reinforcing and better defining safety margins for NUZ-001’s clinical development program”.

Neurizon managing-director Dr Michael Thurn said the company was pleased the FDA responded “with only one straightforward request for additional information”.

Neurizon was up three cents or 23.1 percent to 16 cents with 1.6 million shares traded.

AUSBIOTECH

Ausbiotech says its inaugural Women in Life Sciences Leadership Summit on March 7, 2025 will “advance gender equity in the life sciences sector”.

Ausbiotech said the summit would be held in partnership with Medicines Australia and be followed by its annual Women in Life Sciences lunch.

The industry organization said the summit was “designed to support women making the transition from middle to senior leadership roles” and “a strategic initiative to drive meaningful change by fostering leadership pathways, amplifying diverse perspectives, and dismantling barriers to senior leadership within the industry”.

Ausbiotech said there were almost 3,000 organizations in Australia's life science sector, and there were close to 350,000 biotechnology jobs in Australia.

The organization said although women comprised “almost half of the life sciences workforce, as of 2024, they held only 25 percent of board positions, 18 percent of [chief executive officer] and founder roles, and 29 percent of executive positions”.

Ausbiotech said the summit was “a critical milestone in moving gender equity from aspiration to reality” and the lunch was “designed to support forward-thinking discussions to dismantle barriers, foster leadership pathways, and ensure diverse perspectives shape the industry's future”.

The organization said lunch tickets were $230 for members and $280 for non-members, and that the event would be held at Darling Island Wharf, Doltone House, Sydney on March 7, 2025 from 8am to 12pm (AEDT), with registration available at: https://www.ausbiotech.org/events/event/women-in-life-sciences-2025.