Biotech Daily

Tuesday May 14, 2024

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: AVITA UP 9%; ALCIDION DOWN 6%**

*** QUEENSLAND UNI WINS $750k FOR OVARIAN CANCER BLOOD TEST**

*** AVITA UNAUDITED Q1 REVENUE UP 5% TO $17m**

*** ORTHOCELL: 'STRIATE+ 99% SUCCESSFUL DENTAL REGENERATION'**

*** RACE: 'BISANTRENE, DECITABINE ENHANCE CANCER KILLING IN-VITRO'**

*** PYC STUDY SHOWS PYC-001 SAFE, IN NON-HUMAN PRIMATES**

*** BLUECHIIP, BIOPHARMA SIGN UK DISTRIBUTION DEAL**

*** OSTEOPORE TO PAY $318k FOR SINGAPORE CENTRE**

*** CY BIOPHARMA TO SUPPLY BIOXYNE PSILOCYBIN 'MAGIC MUSHROOMS'**

*** NOXOPHARM TO MANUFACTURE SOF-SKN FOR REGULATORY SUBMISSIONS**

*** IMAGION TO BE REINSTATED TO QUOTATION**

*** BIOXYNE TO RELEASE 1.23b VOLUNTARY ESCROW SHARES**

*** INVESTORS MUTUAL TAKES 6% OF TRAJAN**

*** FIL (FIDELITY) DILUTED TO 8% OF TRIVARX**

*** PHARMAUST LOSES DIRECTOR NEVILLE BASSETT**

MARKET REPORT

The Australian stock market fell 0.3 percent on Tuesday May 14, 2024, with the ASX200 down 23.2 points to 7,726.8 points. Eighteen of the Biotech Daily Top 40 stocks were up, 12 fell, eight traded unchanged and two were untraded.

Avita was the best, up 23 cents or 9.0 percent to $2.78, with 441,201 shares traded. Curvebeam improved 8.6 percent; Neuren climbed six percent; Syntara rose 5.9 percent; Dimerix and Percheron were up four percent or more; Actinogen, Clinuvel, Paradigm and Universal Biosensors were up more than three percent; Cynata, Nanosonics and Orthocell rose more than two percent; Impedimed, Mesoblast and Proteomics were up more than one percent; with Cochlear, Polynovo, Resmed and SDI up by less than one percent.

Alcidion led the falls, down 0.4 cents or 6.35 percent to 5.9 cents, with 2.7 million shares traded. Prescient fell 4.8 percent; 4D Medical, Atomo, Nova Eye and Opthea lost more than three percent; Telix shed 2.2 percent; Cyclopharm, Emvision and Immutep were down more than one percent; with Clarity, CSL and Pro Medicus down by less than one percent.

UNIVERSITY OF QUEENSLAND

The University of Queensland says it has been awarded $750,000 from the Cancer Council Queensland to develop a low-cost, bench-top blood-test for ovarian cancer.
The University of Queensland said Dr Mostafa Kamal Masud, a nano-diagnostics specialist researcher at its Australian Institute of Bioengineering and Nanotechnology, would receive the funds over the next five years to develop the device.
The University said detecting ovarian cancer early was “crucial for patient survival, but extremely difficult given symptoms are often vague and resemble other illnesses, and current screening tests are ineffective”.
The University of Queensland said Dr Masud would develop novel mesoporous nano-structures capable of automatically isolating, purifying and simultaneously detecting cancer biomarkers in a patient’s blood.
The University said Dr Masud believed this biosensors technology would be designed as a device that was compact, portable and simple enough to be operated from a general practitioner’s office.
Dr Masud said the current testing methods for ovarian cancer were “quite expensive and tedious, which makes screening very tricky”.
“And, of course, the longer something like this is left undiagnosed, the more serious the problem becomes,” Dr Masud said.
“That is why many people diagnosed with ovarian cancer have already reached a point where it has spread to other parts of their body,” Dr Masud said.
“Whether someone has access to cancer testing should not be determined by their postcode, or whether they have a certain amount of money,” Dr Masud said.
“Therefore, we are designing a cost-effective device that collects all the information and processes it on the spot, with results available within two hours,” Dr Masud said.
“I have seen how cancer affects people and their families, and I’m inspired by their strength and stories of hope,” Dr Masud said.
“This motivates me to work on finding solutions for this tough disease,” he said.
Cancer Council Queensland chief executive officer Andrew Donne said “these fellowships fund early career cancer researchers, like Dr Masud, who are on the frontline of clinical innovations in cancer detection and treatment.”
“With their innovative approaches and deep personal commitment to improving patient outcomes, these recipients represent the future of cancer research, and we are proud to provide the necessary funds to support their life-saving work,” Mr Donne said.

AVITA MEDICAL

Avita says unaudited revenue for the three months to March 31, 2024 was up 5.25 percent to $US11,104,000 ($A16,825,000), compared to the prior corresponding period.
Avita said revenue was from sales of its Recell spray-on-skin and Permeaderm wound dressing, with increased revenues “largely driven by deeper penetration within individual customer accounts and new accounts for full-thickness skin defect".
The company said that it had received no income from the US Biomedical Advanced Research and Development Authority (BARDA), compared to $US627,000 in the previous corresponding period.
Avita said it had a cash burn of $US26,797,000 for the three months, with cash and cash equivalents of $US16,951,000 at March 31, 2024 compared to $US28,050,000 at March 31, 2023.
Avita was up 23 cents or 9.0 percent to $2.78 with 441,201 shares traded.

ORTHOCELL

Orthocell says a study of 143-implants using its Striate+ dental membrane for guided bone regeneration in dental implant procedures led to a “98.6 percent success rate”.
Orthocell said the study investigated the effect of the Striate+ collagen membrane on patient-related systemic factors, as well as implant and procedure related factors of peri-implant marginal bone level following guided bone regeneration and implant placement.
The company said guided bone regeneration was “a highly successful approach for restoring dental bone defects alongside implant placements” in patients with insufficient bone volume to adequately secure a dental implant.
The company said the procedure had “success rates often higher than 70 percent”.
Orthocell said the study used data from 99 patients receiving at least one dental implant and guided bone regeneration procedure using Striate+ between July 2018 and December 2023; and of the 143 implants studied, 126 implants, or 88.1 percent, had marginal bone level values within the normal physiological limits with two implants failing due to peri-implantitis.
Orthocell said the study results showed “that a desirable level of bone formation and stability was achieved in all areas, demonstrated by the high rate of treatment success”.
The company said the study followed a post-market clinical follow-up study, which was part of its clinical data package for European re-certification of Striate+ under the amended European medical device regulations.
Orthocell was up one cent or 2.6 percent to 40 cents.

RACE ONCOLOGY

Race says a study shows bisantrene with decitabine “significantly improved cancer cell-killing across a broad panel of 143 tumor cell lines than either drug … alone”.
Race said the study, conducted by the Oss, Netherland-based Oncolines BV, screened bisantrene in combination with decitabine across 143 cancer cell lines representing solid and blood cancers originating from more than 20 different human tissues.
The company said decitabine was a nucleoside analog drug used in the treatment of blood cancers including myelodysplastic syndrome and acute myeloid leukaemia but had not shown clinical efficacy in solid tumors.
Race said the study showed decitabine enhanced the cell-killing activity of bisantrene in the most common human cancer types, including solid tumors, with the combination leading to a 91.6 percent improvement, or 131 of 143 samples, in cell lines ($p < 0.0001$).
The company said the results suggested the “clinical utility of decitabine could be expanded beyond blood cancers to solid tumors if used with bisantrene”.
Race said following the study it would optimize the combination of dosing “through in-vivo pre-clinical studies and identification of the best clinical treatment opportunities”.
The company said further pre-clinical studies would “determine the cellular mechanism responsible for the enhanced cancer cell-killing observed with the bisantrene and decitabine combination” and that it would support clinical studies using the combination.
Race chief executive officer Dr Daniel Tillett said the results “open exciting new treatment opportunities for both bisantrene and decitabine”.
“While decitabine has proven its effectiveness in haematological cancers, it has not demonstrated clinical utility in solid tumors, like lung or breast cancer,” Dr Tillett said.
“This new body of work is highly supportive of the results from the University of Newcastle in pre-clinical [acute myeloid leukaemia] models using a combination of bisantrene and decitabine,” Dr Tillett said.
Race was up 10 cents or 6.45 percent to $1.65.

PYC THERAPEUTICS

PYC says its PYC-001 drug candidate for autosomal dominant optic atrophy has “a suitable safety profile”, in non-human primates, and can begin human trials.
Last year, PYC said that in-vitro and in-vivo data supported human trials of PYC-001 for autosomal dominant optic atrophy, pending toxicology studies, and later said a single 16 microgram (16µg) dose was shown to be safe and effective in non-human primate and patient-derived studies (BD: Apr 3, Oct 4, 2023).
Today, PYC said PYC-001 was safe and well-tolerated at 3.0µg, 10µg and 30µg, with a no observable adverse event limit of 30µg per eye, the highest dose evaluated, and it had “all of the information required to submit a regulatory application” for human trials, with a single ascending dose study and human safety and efficacy data in 2025 prior to a new drug application in 2028.
PYC was up half a cent or 5.3 percent to 10 cents with 1.4 million shares traded.

BLUECHIIP

Bluechiip says the Winchester, England-based Biopharma Process Systems Ltd will distribute its wireless sample management tracking system products in the UK.
Bluechiip said Biopharma Group Process Systems was “a leading distributor ad service provider of low-temperature storage solutions, including [liquid nitrogen] vessels and complimentary products, and has divisions covering the UK, France, Ireland and the US”.
The company said Biopharma was in discussions with “several prestigious academic and cell and genetic research centres in the UK, together with major pharmaceutical manufacturing companies for Bluechiip advance sample management solutions”.
Bluechiip managing-director Andrew McLellan said the company’s “products complement the products that Biopharma already distribute”.
“The purchases of low-temperature freezers, whether existing businesses or new facilities, need to manage the valuable samples going into them,” Mr McLellan said.
“Many continue to use handwritten labels and Excel spreadsheets, which we know are sub-optimum,” Mr McLellan said. “By distributing Bluechiip’s products, Biopharma will assist these facilities go to the next level with their sample management practices.”
Bluechiip was unchanged at 0.6 cents.

OSTEOPORE

Osteopore says it will pay $S284,485 ($A318,231) to open its “first global centre of excellence” in partnership with Singhealth at Singapore General Hospital.
Osteopore said a Singapore Government grant would cover 70 percent of the costs, which were payable in the next 30 months and it had the option to extend the partnership for a further 12 months.
Osteopore said it would have a facility at the Singapore General Hospital to co-develop, test, validate, adopt and scale its 3-dimensional bio-mimetic and bio-resorbable implants, which provided “significant benefits including preliminary access to cases, timely design and surgical implantation, and ultimately the platform to improve patient outcomes”.
Osteopore said it had appointed three Singapore General Hospital clinicians to its advisory panel, Prof Andrew Chin, Prof Chew Khong Yik and Dr Henry Soeharno.
The company said the panel would guide the development of a customized medical device framework, using the Hospital as a clinical reference site, to develop the selection criteria for adoption in potential overseas hospitals based on suitability and legislation.
Osteopore was up 0.9 cents or 11.5 percent to 8.7 cents with 32.1 million shares traded.

BIOXYNE

Bioxyne says the Baar, Switzerland-based CY Biopharma AG will supply Breathe Life Sciences psilocybin for Australian and New Zealand clinical and prescribed use.
Bioxyne said the agreement would allow its subsidiary Breathe Life to “manufacture and supply the Australian, New Zealand, US and European clinical trials market with novel psilocybin products, develop proprietary formulations and drug delivery methods and supply it to Australian patients via the authorized prescriber scheme”.
The company said CY Biopharma would “exclusively supply [Breathe] with Psilocybe cubensis fungi”, or ‘magic mushrooms’, for Australia and New Zealand.
Bioxyne said it was “not able to determine the financial contribution from the collaboration at this stage”.
The company said subsidiary Breathe Life Sciences expected “to manufacture the first Australian-made [good manufacturing practice] psilocybin capsules in Australia for commercial supply to approved clinical trials and patients” in the next 90 days.
Bioxyne chief executive officer Sam Watson said “psychedelics are showing significant potential in the treatment of various mental health conditions; a beacon of hope for the large cohort of patients who do not respond to conventional treatment options”.
Bioxyne was up 0.1 cents or 16.7 percent to 0.7 cents.

NOXOPHARM

Noxopharm says it will increase production of its Sof-Skn for lupus to the quality standards that will be required for upcoming regulatory submissions.
Noxopharm said it was increasing manufacturing 100-fold, and the drug would be used to conduct regulatory safety studies “in the coming weeks and months”.
The company said it had begun formulation and optimal dosing testing to maximize the treatment’s efficacy and tolerability in patients with auto-immune disease.
Noxopharm said it had engaged “a range of experts specializing in the supply of pharmacopeia compliant materials and reagents for synthesis and formulation, as well as experts in quality control to ensure that manufacturing of the active ingredient and formulated drug takes place according to set specifications”.
The company said it was testing the formulation of the drug in a range of in-vivo and in-vitro models in order to further refine the characteristics of the formulated drug and dose.
Noxopharm managing-director Dr Gisela Mautner said “scaling up to [good laboratory practice] standards demonstrates that we have great confidence in Sof-Skn as a prospective treatment for lupus, based on a large body of robust data”.
“Reaching this checkpoint in the development process increases the potential for external interest in our technology, as well as the asset’s commercial value,” Dr Mautner said.
“This is a major step in the drug development process,” Dr Mautner said.
Noxopharm was up half a cent or 7.9 percent to 6.8 cents.

IMAGION BIOSYSTEMS

Imagion says following the release of its 2023 annual report, the ASX has told it that it will be re-instated to official quotation once it has appointed a second Australian director.
Last month, the ASX said it had suspended Imagion under Listing Rule 17.5 for “not lodging the relevant period report by the due date” (BD: Apr 2, 2024).
Today, Imagion said it was “currently considering the appointment of an appropriate Australian resident director.
Imagion was in a suspension and last traded at 7.3 cents.

BIOXYNE

Bioxyne says 1,230,000,000 shares will be released from voluntary escrow on May 19, 2024.
Bioxyne said major shareholders holding 1,000,000,000 of those shares agreed to a further voluntary escrow of 12 months to May 19, 2025.
According to its most recent notification of securities, Bioxyne had 1,901,645,398 shares on issue.
Bioxyne chief executive officer Sam Watson said “the agreement to extend the voluntary escrow period by major shareholders is a demonstration of their commitment to the company, which we believe will be well rewarded as we look forward to a year of rapid growth.”

TRAJAN GROUP HOLDINGS

Sydney’s Investors Mutual Limited says it has become a substantial shareholder in Trajan with 9,236,502 shares, or 6.07 percent.
Investors Mutual Ltd said that with Citicorp it bought shares between January 15 and May 13, 2024, with the largest purchase 640,511 shares on May 9 for $417,248, or 65.1 cents a share.
Trajan was up 10 cents or 12.35 percent to 91 cents.

TRIVARX (FORMERLY MEDIBIO)

The Hong Kong-based FIL Limited (Fidelity) says its 656,184,415 shareholding (9.77%) in Trivarx has been consolidated and diluted to 32,809,220 shares (8.01%).
Last year, Trivarx said its annual general meeting approved its 20-to-one consolidation and it had 335,719,543 post-consolidation shares on issue (BD: Oct 18, 27, 2023).
Earlier this month, the company said it had “firm commitments” to raise $2.5 million at 2.5 cents a share in a placement (BD: May 2, 2024).
Trivarx fell 0.3 cents or 10.3 percent to 2.6 cents with 3.3 million shares traded.

PHARMAUST

Pharmaust says non-executive director Neville Bassett has resigned.
Pharmaust said “work has commenced to recruit additional experienced directors who will strengthen the Pharmaust board and bring a renewed focus on good corporate governance, effective strategy, shareholder engagement and commercial acumen as the company enters a transformational stage”.
Pharmaust chair Sam Wright said: “Our thanks go to Neville for his service as a director of Pharmaust for the past five and a half years, during which time he provided calm, well considered counsel to the company”.
“We wish him the best in all future endeavors,” Mr Wright said.
Pharmaust was up 1.5 cents or 8.6 percent to 19 cents with 3.2 million shares traded.