Biotech Daily

Wednesday August 21, 2024

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: ALCIDION UP 10%; RESONANCE DOWN 5%**

*** CRYOSITE REVENUE UP 6% TO $12.6m; PROFIT UP 31% TO $1.8m**

*** BIOXYNE SIGNS UP-TO $28m UNDISCLOSED MARIJUANA GUMMIES DEAL**

*** UNIVERSAL BIOSENSORS $450k ITALY XPRECIA PRIME COAGULANT DEAL**

*** CLINUVEL PHASE III SCENESSE VITILIGO TRIAL DELAYED 8 MONTHS**

*** AMPLIA HAS 5 OF 6 PANCREATIC CANCER RESPONSES**

*** ARTRYA: FDA SALIX FILING EXPECTED 'IN COMING WEEKS'**

*** ARGENT (MGC) MOVES TO CHRONIC WOUNDS**

*** CRYOSITE: LOSES CEO; APPOINTS G-M, EXECUTIVE DIRECTOR**

MARKET REPORT

The Australian stock market was up 0.16 percent on Wednesday August 21, 2024, with the ASX200 up 12.8 points to 8010.5 points. Seventeen of the Biotech Daily Top 40 companies were up, 16 fell and seven traded unchanged.

Alcidion was the best, up 0.8 cents or 9.8 percent to nine cents, with 2.7 million shares traded.

Micro-X and Universal Biosensors climbed more than seven percent; Opthea and Syntara rose more than six percent; Amplia and Cynata were up five percent or more; Clarity and Imugene improved more than three percent; 4D Medical, Immutep and Polynovo rose more than two percent; Aroa, Mesoblast, Neuren and Telix were up one percent or more; with CSL and Pro Medicus up by less than one percent.

Resonance led the falls, down 0.3 cents or five percent to 5.7 cents, with 43,600 shares traded.

Compumedics and Starpharma fell more than four percent; Actinogen. Curvebeam, Proteomics and SDI were down more than three percent; Avita, Cochlear, Dimerix, Emvision, Paradigm and Resmed shed more than two percent; Clinuvel, Cyclopharm, Genetic Signatures and Impedimed were down more than one percent; with Nanosonics down by 0.7 percent.

CRYOSITE

Cryosite says revenue for the year to June 30, 2024 was up 5.7 percent to $12,612,000, with net profit after tax up 30.6 percent to $1,840,000.
Cryosite said revenue was from its clinical trials and biological services logistics business which included “specialist temperature-controlled storage, sourcing, labelling, status management, secondary packaging [and] schedule drug distribution” as well as its cord blood and tissue sample storage services.
The company said it would pay an unfranked dividend of two cents a share to investors on the record date of September 9, payable on October 10, 2024, up 33.3 percent from 1.5 cents a share unfranked dividend in the prior corresponding period.
Cryosite said diluted earnings per share rose 30.4 percent to 3.77 cents, with net tangible asset backing per share down 43.0 percent to 3.34 cents, and it had cash and cash equivalents of $4,703,000 at June 30, 2024 compared to $4,731,000 at June 30, 2023.
Cryosite was up four cents or 5.3 percent to 80 cents.

BIOXYNE

Bioxyne says subsidiary Breathe Life Sciences has an agreement with an unnamed “alternative medicine clinic” to supply up-to $28 million worth of marijuana gummies.
Last year, Bioxyne said it acquired 83 percent of Breathe Life (BD: May 22, 2023).
Today, the company said it had its first commercial purchase orders for tetra-hydro-cannabidiol, or THC, marijuana gummies in July 2024 and had “manufactured and delivered Australia’s first pharmaceutical cannabis pastilles (gummies or edibles) under its good manufacturing practice (GMP) certification”.
Bioxyne said the total purchase orders received between July 12 and August 12, 2024 were valued at about $2 million, including “to one of Australia’s top five alternative authorized prescriber medicine clinics, which has executed an agreement with [Breathe Life Sciences] to manufacture and supply a forecasted minimum $28 million of THC gummy products over the next 24-months.”
Bioxyne said the agreement provided for 50 percent of the order to be paid upfront in the first three months of the contract and the balance on agreed payment terms.
The company said “the gummies were manufactured and packaged as three different products according to three distinct formulations with different dosages of cannabidiol (CBD) and, or delta-9-tetrahydrocannabinol (THC), the two primary active pharmaceutical ingredients in cannabis, each with distinct therapeutic benefits”.
Bioxyne managing-director Sam Watson said Breathe Life was the “first Australian manufacturer to complete a commercial production run of pharmaceutical grade GMP-certified THC gummies”.
Bioxyne was up 0.1 cents or 20 percent to 0.6 cents with 13.1 million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says its Italy distribution partner has a three-year contract worth more than $450,000 for its Xprecia Prime blood coagulation tests.
Last year, Universal Biosensors said it had a two-year contract to supply more than one hundred of its Xprecia Prime blood coagulation diagnostics and 130,000 strips a year to Italy from October 2023 to an unnamed customer (BD: Aug 9, 2023).
Today, the company said the tender was to supply two unnamed health authorities in the north of Italy and included about 45,000 strips a year and 53 Xprecia Prime devices.
Universal Biosensors was up one cent or 7.1 percent to 15 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says it has extended recruitment for its phase III trial of Scenesse for vitiligo and relaxed the inclusion criteria due to current enrolment and patient retention rates.
Last year, Clinuvel said it had dosed the first of up-to 200-patients in its open-label, randomized, phase III trial of Scenesse, or afamelanotide 16mg, for vitiligo or depigmented skin, and it expected recruitment to be completed in about “12 months, depending on the centres’ ability to identify suitable patients” (BD: Oct 18, 2023).
Today, the company said it had made changes to the trial protocol which were expected to result in the last patients being enrolled “by June 30, 2025”.
Clinuvel said the trial was currently studying Scenesse as a combination therapy with standard-of-care narrowband ultraviolet B (NB-UVB) compared to NB-UVB treatment alone, in adult and adolescent vitiligo patients with darker skin complexions.
The company said that the study aimed to show the combination therapy provided “faster, deeper re-pigmentation than NB-UVB monotherapy”.
Clinuvel said that patients assigned to the NB-UVB monotherapy cohort appeared “less motivated to start or complete the 20-week study and [24-week] follow-up period”.
“Given the visible effects and improvement of pigmentation of the combination therapy, patients receiving monotherapy are less willing to adhere to the study protocol,” the company said.
Clinuvel said that an extension to the protocol provided all patients completing the monotherapy would have access to subsequent Scenesse combination therapy.
The company said it had revised the inclusion criteria for the study to “allow enrolment of patients with vitiligous lesions, or depigmentation, on the face including the scalp and neck, broadening the potential eligible population”.
Clinuvel said the primary and secondary endpoints of the study remained unchanged.
The company said the extension “would capture further safety and efficacy data”.
Clinuvel head of clinical affairs Dr Emilie Rodenburger said the company had “worked closely with study sites during setup and initial recruitment to understand where we can enable patient inclusion, as well as encouraging study continuation for those patients who may be disappointed to be enrolled in the monotherapy arm”.
Clinuvel fell 21 cents or 1.5 percent to $13.57 with 104,511 shares traded.

AMPLIA THERAPEUTICS

Amplia says five of six pancreatic cancer patients have had a confirmed partial response in its phase IIa trial, with one more patient response needed to continue trial enrolment.
Earlier this year, Amplia said it had dosed the first of up-to 50 patients in the trial of narmafotinib, or AMP945, with chemotherapy for advanced pancreatic cancer; and later said it had enrolled all 26 patients in the first stage of the trial (BD: Jan 21, Jul 3, 2024).
The company said that once six patients had partial or complete responses an additional 24 patients would be enrolled, for a total of 50 patients (BD: Jul 25, 2024).
Today, Amplia said six patients had shown stable disease at two-month and four-month assessment.
The company said 13 of 26 enrolled patients had been imaged at the four-month time point, meaning that, so far, with five of 13 patients responding, the trial showed narmafotinib had an initial response rate of 38.5 percent.
Amplia managing-director Dr Chris Burns said the continued positive data from the trial was “extremely gratifying and at this rate we remain confident we will re-open recruitment in early October”.
Amplia was up 0.75 cents or 5.8 percent to 13.75 cents with 1.7 million shares traded.

ARTRYA

Artrya says it expects to file a 510(k) application for its Salix coronary anatomy system with the US Food and Drug Administration “in the coming weeks”.
In 2023, Artrya said it had lodged a ‘Q-submission’ to the FDA for Salix, a “key enabling step” in the US regulatory process (BD: May 3, 2023)
Later, the company said that the FDA agreed on a pathway to 510(k) regulatory clearance for Salix (BD: Jun 9, 2023).
This year, Artrya said it lodged a second ‘Q-submission’ to the FDA in preparation for a 510(k) submission for Salix (BD: Jun 7, 2024).
The FDA website did not explain what the ‘Q’ represented but said a ‘Q-Submission’ or ‘Q-sub’ referred to the “system used to track the collection of interactions” and were opportunities for submitters to share information with the FDA and receive input beyond the submission of an application.
Today, the company said following the ‘Q-submission’ meeting it was on-track to submit its application for the approval of Salix to the FDA.
Artrya chief executive officer Mathew Regan said the company was "pleased to report the outcome of our second ‘Q-sub’ meeting with the FDA was positive”.
“The FDA provided valuable feedback and guidance on our upcoming application, confirming our approach is on-track,” Mr Regan said.
“This has validated the cautious approach we have taken to ensure we meet all requirements for the 510(k) application,” Mr Regan said.
Artrya was unchanged at 32 cents.

ARGENT BIOPHARMA (FORMERLY MGC PHARMACEUTICALS)

Argent says it will collaborate with SINTEF to develop anti-microbial active ingredients and nano-formulations of the ingredients for the treatment of chronic wounds.
Argent said the Trondheim, Norway-based Stiftelsen for industriell og teknisk forskning (SINTEF), or the Foundation for Industrial and Technical Research, was “one of Europe’s largest independent research organizations”.
The company said it would “address the critical and unmet clinical challenge of chronic wound management, through nano-formulations as part of [its] ongoing expansion into new therapeutic areas”.
In its initial public offer prospectus lodged to the ASX in 2015, the then MGC said it was “a medical and cosmetics cannabis company, formed in early 2015 to specifically target the global potential of the fast growing medical and cosmetic cannabis markets … [with its] unique [cannabidiol] genetics strain to maximize crop yield”.
Today, Biotech Daily asked executive chair Roby Zomer whether the company would continue its marijuana-related businesses but had not received a reply at the time of publication.
Argent said it hoped the collaboration would lead to “significant advancements in the treatment of chronic wounds, which had “complex challenges, including severe symptoms, antibiotic-resistant infections, impenetrable bio-films, and deteriorating local tissue health”.
The company said the experiments would “initially focus on identifying and selecting the anti-microbial activities of a range of repurposed poly-pharmacological agents endowed with multiple medically beneficial activities”.
Argent said it would cover the costs of the project, which were not expected to have a material impact on expenses, and it would “retain ownership of all project results, including any intellectual property developed”.
Argent was up 16.5 cents or 64.7 percent to 42 cents.

CRYOSITE

Cryosite says chief executive officer John Hogg will retire on October 31, 2024, with Dr Alicia Steel and Andrew Kerr appointed general manager and executive director, respectively.

Cryosite said Andrew Kerr was the son of executive chair Mark Kerr and would transition from non-executive director to executive director, effective from August 20, 2024, to "ensure that the leadership of Cryosite remains focused on delivering the company's operational and strategic objectives".

The company said Mr Kerr would be paid $190,000 a year plus superannuation and receive a performance bonus subject to three performance milestones of $16,666 per milestone.

Cryosite said Dr Steel, who had worked for the company since 2020 and was currently its chief quality officer, would transition to the role of general manager from October 1, 2024.

The company wished Mr Hogg "the best in his retirement".

Cryosite said it had appointed an unnamed "experienced market professional in the role of business development manager" after several years of significant investment in its facility, plant and equipment.