Biotech Daily

Tuesday September 5, 2023

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH UP: GENETIC SIGS UP 9%; PATRYS DOWN 10%**

*** EBR WISE TRIAL: 'RANDOMIZED SUBSET HEART FAILURE EFFICACY'**

*** LBT RECEIVES $849k FEDERAL R&D TAX INCENTIVE**

*** CLINUVEL: EMA WANTS MORE DATA FOR ADOLESCENT SCENESSE**

*** FIVEPHUSION DOSES 1st PHASE Ib/IIa DEFLEXIFOL TRIAL PATIENT**

*** INOVIQ: RESEARCHDX TO SUPPLY EXO-NET TO US**

*** CONTROL BIONICS 315k M-D OPTIONS AGM**

*** MATTHEW HARRIS, BOORIS BELOW 5% OF CLARITY**

*** MERCHANT FUNDS REDUCES, DILUTED TO 8.3% OF BCAL**

*** RESONANCE APPOINTS BENJAMIN CARRUTHERS CFO**

*** LIVING CELL TO LOSE PROF CAROLYN SUE**

*** BCAL APPOINTS SHANE RYAN COO**

*** OSTEOPORE LOSES CO CO-SEC DEBORAH HO**

MARKET REPORT

The Australian stock market slipped 0.06 percent on Tuesday September 5, 2023 with the ASX200 down 4.5 points to 7,314.3 points. Twenty-one of the Biotech Daily Top 40 stocks were up, 12 fell and seven traded unchanged.

Genetic Signatures was the best for the second day, up 4.5 cents or 9.0 percent to 54.5 cents, with 177,299 shares traded. Compumedics rose 8.3 percent; Universal Biosensors was up seven percent; Antisense and Resonance were up more than six percent; 4D climbed 5.7 percent; Micro-X was up 4.8 percent; Imugene, Kazia and Starpharma improved more than three percent; Impedimed rose 2.9 percent; Amplia, Avita, Emvision, Medical Developments, Paradigm and Prescient were up more than one percent; with Cochlear, CSL, Nanosonics, Neuren, Pro Medicus and Telix up by less than one percent.

Patrys led the falls, down 0.1 cents or 10 percent to 0.9 cents, with 161,113 shares traded. Actinogen lost eight percent; SDI was down 6.7 percent; Next Science fell 4.85 percent; Cynata was down 3.85 percent; Mesoblast and Proteomics shed more than two percent; Clinuvel, Immutep, Opthea, Polynovo and Volpara were down more than one percent; with Resmed down 0.4 percent.

EBR SYSTEMS INC

EBR says data from a randomized subset of the Solve-CRT (cardiac re-synchronization therapy) trial of its Wise device shows efficacy for heart failure.

In May, EBR said its 183-patient Wise (wireless stimulation endocardially) device pivotal trial met both the primary efficacy and safety endpoints with statistically significant improvement against pre-set benchmarks (BD: May 22, 2023).

The company said that on September 2, 2023 it presented data to the Asia-Pacific Heart Rhythm Society conference in Hong Kong that showed two randomized populations using the Wise system had “clinically and statistically significant” results.

EBR said that of the original 183 patients in the Solve-CRT study, 108 were enrolled in the randomized phase, with all cardiac patients received the Wise implant and were randomized in a one-for-one ratio to either the treatment group with the Wise system switched on or to the control group with the Wise system switched off.

The company said the patient groups in the sub-study included patients who were previously untreatable (PU), high risk upgrades (HRU), and non-responders (NR).

EBR said that the outcome of the randomized sub-study reinforced “the positive results previously reported for Solve which exceeded both efficacy and safety thresholds”.

The company said that the Wise technology was “the world’s only wireless, endocardial, inside the heart, pacing system in clinical use for stimulating the heart’s left ventricle”.

EBR said that a wireless system had been “a goal of cardiac pacing companies, since internal stimulation of the left ventricle [was] thought to be a potentially superior, more anatomically correct pacing location”.

The company said that its Wise technology enabled “cardiac pacing of the left ventricle with a novel cardiac implant that is roughly the size of a large grain of rice … [with] the need for a pacing wire on the outside of the heart’s left ventricle, and the attendant problems, [were] potentially eliminated”.

EBR said that in a group of 99 patients, including non-responders, previously untreatable patients and “high risk upgrade” patients, 47 had a 14.6 percent improved heart function, compared to the 52-patient control group that had a 5.2 percent improvement ($p = 0.005$).

The company said that in a subset of patients, excluding non-responders, 22 treated patients had an 18.2 percent improved heart function, compared to the 29-patient control group that showed a 3.1 percent improvement ($p = 0.002$).

EBR chief executive officer John McCutcheon said: “We are immensely proud of these positive results from our randomized sub-study, which show our system generating a statistically significant benefit to patients who used our technology.”

“The strong result supports our findings from the Solve-CRT trial and demonstrates the efficacy and safety of our Wise-CRT system,” Mr McCutcheon said.

Mr McCutcheon said the company would continue to advance its pre-market approval application to the US Food and Drug Administration and looked forward to FDA approval.

“We remain focused on progressing and executing our commercialization strategy as we look to significantly improve the lives of many patients suffering from cardiac arrhythmia and heart failure,” Mr McCutcheon said.

EBR fell two cents or 2.3 percent to 85 cents.

LBT INNOVATIONS

LBT says it has received $848,673 from the Australian Taxation Office under the Federal Government Research and Development Tax Incentive Program.

LBT said the incentive related to expenditure for the year to June 30, 2023.

LBT was unchanged at 1.8 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says the European Medicines Agency wants more data for its application to expand Scenesse to 12-to-17-year-old erythropoietic protoporphyria (EPP) patients.
Last year, Clinuvel said it had applied to the European Medicines Agency (EMA) to expand the Scenesse, or afamelanotide 16mg, label to include adolescent patients with erythropoietic protoporphyria (BD: Sep 5, 2022).
Today, the company said that it would conduct a Scenesse study on 12 European adolescent patients and expected to report results to the EMA in 2024.
Clinuvel chief scientific officer Dr Dennis Wright said there was “a growing pool of adolescent patients treated under expert supervision” that expanded the company’s database of safety and effectiveness data.
“Although, there is a good scientific reason to allow adolescent patients access to Scenesse now, the EMA maintains its risk threshold for the drug product notwithstanding its safe use [during] the past two decades,” Dr Wright said.
“Once we have obtained additional clinical data, anticipated in 2024, the drug is expected to be available to all adolescent patients, giving them an approved treatment option for the first time,” Dr Wright said.
“The convenience of being treated once every two months is reported to be an advantage for adolescent patients,” Dr Wright said. “It is estimated that 10 percent of the total EPP European population are of 12-to-18 years of age.”
Clinuvel fell 35 cents or 1.9 percent to $17.80.

FIVEPHUSION PTY LTD

Fivephusion says it has dosed the first of up-to 34 patients in its phase Ib/IIa trial of Deflexifol for paediatric ependymoma and other childhood brain cancers.
Earlier this year, the company said it would conduct a dose-ranging, safety and efficacy phase Ib/IIa trial of its Deflexifol combination for gliomas and ependymoma, a central nervous system tumor (BD: Jun 14, 2023).
At that time, Fivephusion executive director Dr Bill Ketelbey told Biotech Daily that Deflexifol was a combination of the chemotherapy drugs 5- fluorouracil and its bi-modulator leucovorin, a drug that potentiates 5-fluorouracil anti-tumor activity, for the treatment of solid tumors.
“Deflexifol is a novel reformulation of 5-fluorouracil and leucovorin, with cyclodextrin, which for the first time, allows for the concurrent co-administration of these two pharmacologically incompatible anticancer drugs,” Dr Ketelbey said.
Today, Fivephusion said the first part of the study would determine safety, tolerability, maximum dose and a recommended phase II does in child patients; and the second part would evaluate the drug’s anti-tumor activity, response rate and overall survival rate.
Fivephusion said “all major paediatric oncology centers in Australia were participating in the trial” which was sponsored by the Australian and New Zealand Children’s Haematology/Oncology Group and supported by the Kids with Cancer Foundation and the Robert Connor Dawes Foundation.
The company said the priority indications for Deflexifol were paediatric ependymoma and first-line metastatic colorectal cancer, with a phase III registration trial of the drug for MCRC planned to start by 2025.
Fivephusion managing-director Dr Christian Toouli said treating the first patient was “a very important milestone for the development of Deflexifol as a promising new therapy for paediatric brain cancers”.
Fivephusion is a private company.

INOVIQ

Inoviq says the Irvine, California-based Researchdx Inc will supply Inoviq's Exo-Net exosome capture diagnostic technology for sample processing in the US.
Inoviq said Researchdx, a contract diagnostics organization that offered partnership for the development of diagnostics, would sell contract research services featuring the Exo-Net technology to customers in the US.
The company said under the agreement customers would be offered a range of contract research services from Researchdx using its Exo-Net tool for exosome isolation, biomarker discovery and diagnostic development.
Inoviq did not disclose the commercial terms of the agreement.
Inovid said that the Researchdx agreement "builds on the previously announced joint marketing agreement for … Exo-Net exosome capture technology and Promega nucleic acid purification systems (BD: Jul 6, 2023).
Today, Inoviq chief executive officer Dr Leearne Hinch said the agreement was "an important, strategic move that enables us to provide high quality Exo-Net services to customers in the US, Australia and elsewhere, expanding our revenue generation opportunities for Exo-net."
Inoviq fell one cent or 1.5 percent to 65 cents.

CONTROL BIONICS

Control Bionics says its annual general meeting will vote to issue managing-director Jeremy Steele 315,389 options exercisable at 9.5 cents each within five years.
Control Bionics said that shareholder would vote to approve the remuneration report, re-elect chair Roger Hawke and Prof Robert Heard as directors, approve the employee share option plan and the 10 percent additional share issue capacity.
The meeting will be held at the University of New South Wales city campus, Level 7, 1 O'Connell St, Sydney, October 10, 2023 at 10.30am (AEDT).
Control Bionics was unchanged at 7.6 cents.

CLARITY PHARMACEUTICALS

Matthew Harris says he and Boorris Pty Ltd have ceased their substantial holding in Clarity, selling 1,750,000 shares for $1.00 a share on September 1, 2023.
In 2021, the former Clarity chief executive officer Mr Harris said he, Boorris and TM Ventures Pty Ltd became substantial with 14,078,620 shares (5.50%) (BD: Aug 25, 2021).
Biotech Daily calculates Mr Harris holds 12,328,620 shares (4.7%) of the company.
Clarity fell two cents or 1.95 percent to $1.005.

BCAL DIAGNOSTICS

Perth's Merchant Funds Management Pty Ltd says it has reduced and been diluted in its holding in Bcal from 20,000,000 shares (9.64%) to 19,597,348 shares (8.28%).
Merchant Funds said that between August 1, 2022 and September 1, 2023 it was diluted due to a share issue in August, 2023 and it bought and sold shares, on market, with the single largest sale of 3,225,000 shares for $199,290 or 6.2 cents a share.
Last week, Bcal said it raised $2.4 million in an oversubscribed placement at 10 cents a share, and hoped to raise $500,000 in a share purchase plan (BD: Aug 28, 2023).
Bcal was up half a cent or five percent to 10.5 cents.

RESONANCE HEALTH

Resonance says it has appointed Benjamin Carruthers as its chief financial officer and expects him to begin the role in October 2023.
Resonance said Mr Carruthers was previously SFM Marine general manager and had a Korda Mentha executive director, and would have a base salary of $225,000 a year, with short term incentives of up-to 20 percent of fixed remuneration and be eligible to participate in a long-term incentive scheme.
According to his Linkedin page, Mr Carruthers held a Bachelor of Commerce and a Bachelor of Arts from the University of Melbourne.
Resonance was up 0.4 cents or 6.45 percent to 6.6 cents.

LIVING CELL TECHNOLOGIES

Living Cell says that Prof Carolyn Sue "will cease all consulting activities with the company on October 4, 2023".
Living Cell said that the NTCell encapsulated pig choroid brain cells for Parkinson's disease scientific review would continue under chief operating officer Dr Belinda Di Bartolo who was appointed to the project in 2021.
The company said that Dr Di Bartolo would be assisted by a team appointed to the scientific advisory board.
Living Cell said it extended "its appreciation to Prof Sue for the contribution she has made towards the NTCell project".
Living Cell was unchanged at 1.5 cents.

BCAL DIAGNOSTICS

Bcal says it has appointed Shane Ryan as its chief operating officer, effective from September 21, 2023.
Bcal said Mr Ryan would be responsible for the operation and administration of its clinical affairs, physician relationships, clinical product marketing, promotion, strategy, and business development.
The company said Mr Ryan was previously Genesis Care's head of strategy and innovation, had more than 20 years' experience in oncology and in particular breast cancer, and had worked in clinical operations, services development and surgery for 10 years at the Peter MacCallum Cancer Centre.
According to his Linkedin, Mr Ryan held a Bachelor of Arts and a Master of Business Administration from Victoria University.

OSTEOPORE

Osteopore says joint company secretary Deborah Ho has resigned, effective from August 31, 2023.
Osteopore said the joint company secretary Kellie Davis would continue as the primary person responsible for communication with the ASX.
Osteopore was unchanged at 6.8 cents.