Biotech Daily

Wednesday March 8, 2023

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: MESOBLAST UP 14%; PHARMAXIS DOWN 8%**

*** NUHEARA RAISES $3m, REALTEK 'CORNERSTONE' $600k**

*** PROTAGONIST: JNJ-2113 REDUCES PSORIASIS LESIONS**

*** FDA APPROVES COMPUMEDICS OKTI NEURO EEG**

*** CHINA ORDERS 40 TRUSCREEN CERVICAL CANCER DEVICES**

*** ALTERITY DOSES 1st ITALIAN ATH434 MSA PATIENT**

*** FDA ACCEPTS MESOBLAST REMESTEMCEL-L GVHD RE-SUBMISSION**

*** BIONOMICS REQUESTS BNC210 'RESULTS ANALYSIS' TRADING HALT**

*** ORTHOCELL APPOINTS PROF RAVI THADHANI DIRECTOR**

*** BIOCURATE LOSES CEO DR BATES; COO, CO SEC MS PETERSON; $20m**

*** IMPEDIMED TO LOSE CCO MIKE BASSETT**

MARKET REPORT

The Australian stock market fell 0.77 percent on Wednesday March 8, 2023, with the ASX200 down 56.9 points to 7,307.8 points. Sixteen of the Biotech Daily Top 40 stocks were up, 16 fell, seven traded unchanged and one was untraded.

Mesoblast was the best, up 13 cents or 14.05 percent to $1.055 with 11.6 million shares traded. Nanosonics climbed 7.5 percent; Polynovo was up 5.4 percent; Compumedics and Kazia improved more than three percent; Emvision and Neuren rose more than two percent; Actinogen, Antisense, Avita, Cochlear, Immutep, Pro Medicus, Proteomics and Telix were up more than one percent; with CSL, Cyclopharm and Medical Developments up by less than one percent.

Pharmaxis led the falls, down 0.4 cents or 7.7 percent to 4.8 cents, with 73,334 shares traded; followed by Prescient down 7.6 percent to 9.7 cents, with 1.6 million shares traded. Atomo, Resonance and Universal Biosensors lost six percent or more; Amplia and Dimerix fell four percent or more; Impedimed, Starpharma and Volpara were down more than three percent; Nova Eye shed 2.6 percent; Alcidion, Clinuvel and Paradigm were down more than one percent; with Genetic Signatures, Next Science and Resmed down by less than one percent.

NUHEARA

Nuheara says it has “firm commitments” to raise $3 million at 17 cents a share “cornerstoned” by $600,000 from existing shareholder Taiwan’s Realtek.
Nuheara said the placement price of 17 cents a share was a 14.6 percent discount to the five-day volume weighted average price to February 28, 2023.
The company said the commitments would allow it “to lodge its half year financial accounts to December 31, 2022 and resume trading on the ASX”.
Nuheara managing director Justin Miller said the funds would “provide working capital to ramp up production for the over the counter roll out of our [US Food and Drug Administration] cleared hearing aids in the US”.
Nuheara said it had appointed Sydney-based Petra Capital Pty Ltd as sole lead manager and bookrunner for the placement.
Nuheara was in a suspension and last traded at 20.5 cents.

PROTAGONIST THERAPEUTICS

Protagonist says its 255-patient, phase IIb trial of JNJ-2113 met its primary endpoint, with a statistically significant reduction of psoriasis lesions at week-16 compared to placebo.
The Brisbane and Newark California-based Protagonist said that treatment with its oral interleukin-23 receptor antagonist peptide drug JNJ-2113 (formerly PN-235) was “well tolerated, with no meaningful difference in frequency of adverse events across treatment groups” for adult patients with moderate-to-severe plaque psoriasis.
The company said that the results showed a significantly greater proportion of patients who received JNJ-2113 achieved a 75 percent improvement in skin lesions as measured by the psoriasis area and severity index. compared with placebo, but did not provide the data, nor a “p” value.
Protagonist said a clear dose response was observed across an eight-fold dose range and “treatment was well tolerated with no meaningful difference in frequency of adverse events across treatment groups versus placebo”.
The company said the trial was in collaboration with Janssen Biotech, a Johnson and Johnson company.
Protagonist said it would take JNJ-2113 to a phase III study, which would qualify it for milestone payments of $US50 million, and meeting primary endpoints in that study would qualify it for a further $US115 million milestone payment.
Protagonist chief executive officer Dr Dinesh Patel said that “a full measure of JNJ-2113 should be evident when the Frontier 1 phase IIb data are shared at an upcoming medical conference”.
“It is our expectation that JNJ-2113 will progress into a phase III registrational study in plaque psoriasis on the strength of these data,” Dr Patel said.
“We are excited about JNJ-2113's potential prospects across the spectrum of additional IL-23 mediated diseases,” Dr Patel said.
“We see this as a watershed moment for Protagonist, the industry and patients by successfully targeting a systemic immune-modulatory IL-23 monoclonal antibody pathway through an oral peptide antagonist,” Dr Patel said.
Protagonist said that JNJ-2113 was in multiple trials, led by Janssen, including a long-term extension study in adults with moderate to severe plaque psoriasis, a phase IIa trial testing a delayed release JNJ-2113 tablet versus placebo and a phase I trial of an immediate release formulation of JNJ-2113 in healthy Chinese adult participants.
On the Nasdaq, Protagonist was up $US7.89 or 51.9 percent to $US23.09 ($A35.02) with 1.1 million shares traded.

COMPUMEDICS

Compumedics says the US Food and Drug Administration has granted 510(k) approval for Okti electro-encephalogram (EEG) amplifier for diagnosing brain disorders.

Compumedics said that the high-density ambulatory Okti EEG combined "several different channel interfaces into a compact hand-held format … [enabling] patients to undergo high resolution studies with the flexibility to be mobile".

The company said that Okti could be used for routine and long-term EEG epilepsy monitoring as well as other brain disorders and its "wireless and high-definition capabilities will improve clinical workflows and the patient experience".

Compumedics said Okti was approved for both paediatric and adult applications and had "up-to 72 hours battery life, with hot swappable batteries, to ensure continuous recording".

Compumedics executive chair Dr David Burton told Biotech Daily that clinic or hospital neurology patients normally would be wired to a device and monitored over a period of time, "typically 24 hours or more" but Okti's wireless capability enabled the patient to freely move around with the device while the data was continuously captured.

Dr Burton said that the Okti device was the most advanced technology that the company had developed and would provide greater access to the US.

The company said the approval was "a significant milestone for … [its] core business growth goal of expanding its neurological monitoring market share in the US".

Compumedics said it would sell Okti systems across the US for between $US50,000 and $US250,000 depending on the number of devices ordered and final Okti configuration, with large long-term monitoring sites expected to pay more than $US1 million.

The company said the potential US EEG market was estimated at $US400 million, and the company aimed to target one-to-two percent of the market.

Dr Burton said the company was "pleased to have achieved this important milestone for the Okti EEG amplifier range".

"Receiving 510(k) clearance from the FDA, whilst expected, is nevertheless satisfying, and validating," Dr Burton said.

"In addition to the technical accomplishments achieved by the Company, it represents a key milestone in relation to a major objective to expand our EEG market share in the US," Dr Burton said.

Compumedics said that the Okti system had both Conformité Européenne (CE) mark and Australian Therapeutic Goods Administration approval.

Compumedics was up half a cent or 3.45 percent to 15 cents.

TRUSCREEN GROUP

Truscreen says Beijing Siweixiantai Tech Co has ordered 40 of its cervical cancer screening devices, expected to be delivered in April 2023.

Truscreen said that following long Covid-related delays, the first devices were installed in Beijing's People's Liberation Army General Hospital in February 2023.

The company did not state the commercial terms of the sale.

Truscreen said that it had won tenders for the cervical cancer screening device at seven hospitals, had 13 installations pending and 23 hospitals where it had been approved and was awaiting tender outcomes.

The company said that a further 78 hospitals where obstetric and gynaecologic department acceptance had been received, were waiting for the next stage of hospital approval.

Truscreen was up 0.3 cents or 11.1 percent to three cents.

ALTERITY THERAPEUTICS

Alterity says it has dosed its first Italian patient in the 60-patient, phase II, randomized, double-blind, controlled trial of ATH434 for multiple system atrophy (MSA).
Last year, Alterity said it had dosed the first patient of the 60 patients, in the 12-month trial exploring the effect of ATH434 treatment on biomarkers such as aggregating alpha-synuclein and excess iron, both of which it said were important contributors to multiple system atrophy pathology (BD: Jul 6, 2022).
In January, the company said patients would receive one of two dose levels of ATH434 or placebo for 12 months, and the data would inform the design of a planned phase III study (BD: Jan 25, 2023).
Today, the company's chief executive officer Dr David Stamler said the company was "pleased to announce that our first participant in Europe has been dosed in our phase II clinical trial as we look to bring a potential new treatment option to individuals living with MSA".
"We continue to make excellent progress advancing the trial in several countries," Dr Stamler said.
Alterity was up 0.05 cents or 5.9 percent to 0.9 cents with 5.6 million shares traded.

MESOBLAST

Mesoblast says the US Food and Drug Administration has accepted its resubmission for Remestemcel-L in children with steroid-refractory acute graft versus host disease.
Last month, Mesoblast said it had resubmitted its remestemcel-L biological licence application to the FDA for acute graft versus host disease in children (BD: Feb 1, 2023).
In 2020, Mesoblast said the FDA required a further trial of remestemcel-L for steroid refractory acute graft versus host disease (BD: Oct 2, 2020). Earlier that year, the FDA Oncologic Drugs Advisory Committee voted nine to one in favor that the available data supported the efficacy of remestemcel-L, or Ryoncil for paediatric steroid-refractory acute graft-versus-host disease (BD: Aug 14, 2020).
Today, the company said the resubmission contained information required by the FDA in the complete response letter it received in September 2020.
Mesoblast said that the FDA had set a US Prescription Drug User Fee Act (PDUFA) goal date of August 2, 2023.
Mesoblast said that, if approved, Remestemcel-L would be the first allogenic off-the-shelf cellular medicine to be approved by the FDA and the first therapy for children under 12-years-old with steroid-refractory acute graft versus host disease.
Mesoblast was up 13 cents or 14.05 percent to $1.055 with 11.6 million shares traded.

BIONOMICS

Bionomics says it has requested a trading halt pending an announcement "in relation to the full results analysis from the Prevail phase II study of BNC210" for social anxiety.
Last year, Bionomics said it had begun the randomized, double-blind, controlled, single-dose of 225mg or 675mg study of BNC210 for acute treatment of social anxiety disorder, with top-line results expected by the end of 2022 (BD: Jan 16, 2022).
Trading will resume March 10, 2023 or on an earlier announcement.
Prior to 11.55am trading halt, Bionomics was up 0.9 cents or 33.3 percent to 3.6 cents with 7.6 million shares traded.

ORTHOCELL

Orthocell says it has appointed Prof Ravi Thadhani as an independent non-executive director.

Orthocell said Prof Thadhani had more than 30 years of experience, most recently as a professor of medicine at Harvard Medical School, as well as serving on US Food and Drug Administration advisory committees in the Musculo-skeletal, cardio-vascular and renal sectors providing guidance to the FDA and companies on regulatory requirements for medical devices and therapeutics.

The company said that Prof Thadhani had been an adviser to Sandoz, Shire, Novartis, Celgene, Bayer and Reata and was currently the head of health affairs and vice-chair of the Emory Healthcare.

According to his Linkedin page, Prof Thadhani held a Bachelor of Science from Indiana's University of Notre Dame, a Doctor of Medicine from the Philadelphia-based University of Pennsylvania and a Master of Public Health from Harvard School of Public Health.

Orthocell was unchanged at 39 cents.

BIOCURATE

Biocurate says chief executive officer Dr Damien Bates and chief operating officer and company secretary Linda Peterson have resigned and it has $20 million in funding.

Biocurate said that it had begun a search for replacements for Dr Bates and Ms Peterson with Dr Chris Chan promoted to research and development executive director.

The University of Melbourne and Monash University joint venture, supported by the Victoria Government, said it had secured $10 million in renewed funding commitments from each of the two universities, totaling $20 million.

Biocurate said that combined with existing funds, the renewed commitments allowed the continued delivery for several years to assist the Victorian and Australian biotechnology sector by translating early-stage research into pre-clinical pharmaceutical candidates.

The company said Dr Bates had been the chief executive officer since 2021 and would depart in April to join Novo Nordisk as its head of cell therapy development.

Biocurate chair and former Victoria Premier and Treasurer John Brumby said that the renewed funding was "a vote of confidence and gives Biocurate the runway to continue its important work in translating discoveries from Victoria's world-class bioscience laboratories into high quality therapies that can save and improve people's lives".

IMPEDIMED

A company update from Impedimed managing-director Rick Valencia said that the role of Australian chief commercial officer Mike Bassett had been made redundant.

Mr Valencia said it was a "difficult decision" and "all of us at Impedimed commend Mike Bassett for his dedication to the company and are appreciative of his tremendous efforts over the past few years".

Mr Valencia said Impedimed was focused "on achieving our growth targets … [and] continue to review our overall operational structures to ensure we operate as efficiently as possible".

Impedimed fell 0.2 cents or 3.3 percent to 5.8 cents with 2.7 million shares traded.