Biotech Daily

Wednesday February 14, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ACTINOGEN UP 10%; NOVA EYE DOWN 24%**

*** NOVA EYE PLACEMENT, INSTO OFFER RAISE $5.1m; $2.9m RETAIL TO GO**

*** PAINCHEK UNDERWRITTEN SHARE PLAN FOR $2.5m; $2.5m PLACEMENT**

*** REGENEUS TO BECOME 'CAMBIUM BIO'**

*** SYNTARA TRIALS SNT-5505 FOR MDS BLOOD CANCER**

*** PHARMAUST DOSES 1st EXTENSION MND MONEPANTEL PATIENT**

*** IMPEDIMED: MASCC RECOMMENDS BIS FOR LYMPHOEDEMA**

*** MILFORD BELOW 5% OF IMMUTEP**

*** IMMUTEP APPOINTS ANNE ANDERSON DIRECTOR**

*** EPSILON DIRECTORS JOHN FEW, WILSON MIN 'REMOVED'**

MARKET REPORT

The Australian stock market fell 0.74 percent on Wednesday February 14, 2024, with the ASX200 down 55.9 points to 7,547.7 points. Fifteen of the Biotech Daily Top 40 stocks were up, 17 fell, seven traded unchanged and one was untraded.

Actinogen was the best, up 0.4 cents or 10.3 percent to 4.3 cents, with 10.8 million shares traded. Imugene and Syntara (Pharmaxis) improved more than four percent; Clarity and Starpharma climbed more than three percent; 4D Medical, Cyclopharm, Impedimed, Resonance and SDI rose more than two percent; Avita, Cochlear and Proteomics were up one percent or more; with Medical Developments, Nanosonics and Pro Medicus up by less than one percent.

Nova Eye led the falls, down 6.5 cents or 23.6 percent to 21 cents, with 2.2 million shares traded. Compumedics lost 9.6 percent; Curvebeam and Cynata were down more than eight percent; Paradigm and Percheron (Antisense) shed more than six percent; Next Science fell 4.4 percent; Atomo and Universal Biosensors were down more than three percent; Alcidion, Dimerix, Polynovo and Prescient shed two percent or more; Clinuvel and Mesoblast were down more than one percent; with CSL, Neuren, Resmed and Telix down by less than one percent.

NOVA EYE

Nova Eye says its placement and one-for-eight institutional rights offer raised $5.1 million at 21 cents a share, with an underwritten $2.9 million retail offer to follow.
Earlier this week, Nova Eye said it hoped to raise $8.0 million (BD: Feb 12, 2024).
Today, the company said chair Victor Previn and managing-director Thomas Spurling had taken up their entitlements and following the raise it would have about $10.0 million cash.
Nova Eye fell 6.5 cents or 23.6 percent to 21 cents with 2.2 million shares traded.

PAINCHEK

Painchek says it will raise $2.5 million in a fully-underwritten share purchase plan and intends to raise a further $2.5 million in a placement following the share plan.
Painchek said the share plan price would be a 20 percent discount to the volume weighted average price of its shares for the five-days prior to the issue date of March 11, 2024.
The company said the funds would be used for US commercialization and regulatory clearance for its adult pain facial recognition software application, commercializing its infant application, strengthen its cyber security and complete a technology upgrade.
Painchek said the plan had a record date of February 13, would open on February 16 and close on March 4, 2024, and that subject to US Food and Drug Administration clearance it would raise more funds to commercialize the adult application in North America and Europe and to expand the international commercialization of the infant application.
Canaccord Genuity was the underwriter and intended to lead the placement.
Painchek fell 0.4 cents or 11.8 percent to three cents with 1.3 million shares traded.

REGENEUS

Regeneus says it will acquire the Atlanta, Georgia-based Cambium Medical Technologies LLC and become Cambium Bio, subject to shareholder and other approvals.
Last year, Regeneus said it would merge with Cambium Medical Technologies LLC for its Elate Ocular for dry eye disease (BD: Apr 28, 2023).
At that time, the company said it would further develop Elate Ocular which had completed a 64-patient phase I/II trial “with highly differentiated clinical readouts”.
Regeneus said the US Food and Drug Administration had approved two Cambium investigational new drug applications for phase III trials in chronic dry eye disease and dry eye disease in ocular graft versus host disease
Today, the company said it expected the transaction for close in March 2024.
Regeneus said it had 306,436,915 shares on issue and would issue a further 306,436,915 shares to Cambium shareholders, and pay 5.5 percent of future revenue royalties for Cambium’s existing Elate Ocular for dry eye disease, so long as the development costs did not exceed an aggregate of $US20.5 million ($A31.7 million).
The company said its director Leo Yao Lee would step down and it would appoint Cambrium Terence Walts, Dr Edmund Waller and Sebastian Tseng to its board.
The company said Karolis Rosickas would continue as chief executive officer, with Mr Walts as head of US activities, Dr Waller as chief scientific officer and Dr Neera Jagirdar as director of medical, clinical and regulatory affairs.
Regeneus said it was “considering immediate capital needs to support Cambium Bio’s future activities and working capital needs, including phase III trials for Elate Ocular”.
The company said it had received in principal confirmation from the ASX that Listing Rules 11.1.1, 11.1.2 and 11.1.3 did not apply to the proposed transaction.
Regeneus climbed 0.1 cents or 16.7 percent to 0.7 cents.

SYNTARA (FORMERLY PHARMAXIS)

Syntara says it will conduct an up-to 39-patient, phase II trial of SNT-5505 (PXS-5505), with chemotherapy for myelodysplastic syndrome (MDS), a type of blood cancer.
Last year, the then Pharmaxis said it was conducting a phase II trial of PXS-5505 for myelofibrosis, had dropped liver cancer as a potential indication of the drug and that the drug had increased pancreatic cancer survival rates in mice (BD: Apr 12, Aug 29, 2023).
Today, Syntara said the trial would be conducted with the University of Newcastle and Australasian Leukaemia and Lymphoma Group and would be assisted by an $830,000 grant from the Federal Government's Medical Research Future Fund.
The company said the trial would evaluate nine transfusion-dependent patients with low and intermediate risk myelodysplastic syndrome by administering a fixed dose of SNT-5505 and two different doses of a hypomethylating agent, a type of chemotherapy.
Syntara said that following the initial nine patients, it would enrol a dose expansion phase of up-to 30 patients who would receive treatment for six months on the dose combination selected in the first phase based on tolerability and efficacy.
The company said endpoints included the reduction in transfusion dependency, haematological parameters and quality of life, with results from the dose escalation phase including safety and preliminary efficacy expected by July, 2025.
Syntara said it expected to commence the trial later this year, and that it would contribute $700,000 to the dose escalation and expansion phases of the study, which were expected to run for three years, as well as supplying the study drug.
Syntara was up 0.1 cents or 4.55 percent to 2.3 cents with 1.4 million shares traded.

PHARMAUST

Pharmaust says it has dosed the first of up-to 12 patients in its open-label, phase I, 12-month extension study of monepantel for motor neuron disease (MND).
Pharmaust said the extension study would investigate the long-term safety, tolerability and efficacy of monepantel in patients with motor neuron disease or amyotrophic lateral sclerosis who had previously completed the initial phase I study.
The company said all 12 phase I patients had elected to continue monepantel treatment through a compassionate-use program and were willing to participate in the extension study where they will be administered daily 10mg/kg doses of monepantel for 12 months.
Pharmaust said its statistical consultant specialist partner Berry Consultants had conducted an analysis of baseline survival rates from historical control data.
The company said Berry's "conservative sensitivity analyses identified the one-year study survival rate estimate of 67.7 percent with a 95 percent confidence interval".
Pharmaust said that "considering differential diagnosis durations, the probability estimates of all 12 phase I … patients surviving today without treatment are less than 0.1 percent".
Pharmaust chief executive officer Dr Michael Thurn said "initiation of the [open-label extension] study is a significant milestone for Pharmaust and the 12 patients who began their treatment journey with monepantel in October 2022."
"It is remarkable and satisfying to know that all 12 patients are still alive and capable of participating in this important extension study," Dr Thurn said.
"The survival statistics based on these 12 patients are extremely encouraging for the company and the wider patient population with [motor neuron disease or amyotrophic lateral sclerosis]," Dr Thurn said.
"This provides an exciting backdrop ahead of the release of the top-line data from the recently completed phase I … study, due by the end of February 2024," Dr Thurn said.
Pharmaust was up 2.5 cents or 14.3 percent to 20 cents with 3.4 million shares traded.

IMPEDIMED

Impedimed says the Multinational Association of Supportive Care in Cancer (MASCC) recommends using bio-impedance spectroscopy (BIS) to identify lymphoedema.

Impedimed said the MASCC was an “organization dedicated to improving the lives of people with cancer and their families by advancing supportive care research, education and clinical practice”.

The company said that its Sozo was “the only [US Food and Drug Administration] cleared and clinically validated [bio-impedance spectroscopy] system for the early detection and monitoring of lymphoedema”.

Impedimed said the MASCC guidance was made by a panel of participants from Japan, the US, Hong Kong, Canada, Italy, Denmark, Australia, Spain and the UK.

The company said that the recommendation supported its multi-national sales efforts.

Impedimed said the Association specifically named bio-impedance spectroscopy “as a recommended option to identify early signs of lymphoedema along with specific thresholds for [its] L-Dex”.

The company said Sozo was already available in the US, Australia, New Zealand, Hong Kong, the UK, Ireland, Denmark and Sweden.

Impedimed said the MASCC guidelines were published in The Lancet and was at: https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(24)00020-8/fulltext.

Impedimed was up 0.2 cents or 2.5 percent to 8.3 cents with 3.3 million shares traded.

IMMUTEP

Milford Asset Management says it has ceased its substantial shareholding in Immutep having sold 11,300,000 shares on market for $4,172,806, or 36.9 cents a share.

The Auckland, New Zealand-based Milford said that between July 11 and November 1, 2023 it bought 1,865,477 shares for $541,530, or 29.0 cents a share and from December 18, 2023 to February 13, 2024 it sold the 11,300,000 shares.

Last year, Milford said it became substantial in Immutep with 61,555,077 shares or 5.339 percent (BD: Jun 9, 2023).

According to its most recent notice, Immutep had 1,188,834,559 shares on issue, meaning that Milford’s remaining 52,120,554 shareholding amounts to about 4.38 percent of the company

Immutep was unchanged at 36.5 cents.

IMMUTEP

Immutep says it has appointed Anne Anderson as an independent non-executive director, effective from today.

Immutep said Ms Anderson was currently non-executive director of BT Funds Management, had previously been on the board of an unlisted subsidiary of Ingenia Communities Group and held managing-director roles with UBS Asset Management.

The company said Ms Anderson held a Bachelor of Economics and a Master of Applied Finance from Macquarie University.

EPSILON HEALTHCARE

Epsilon administrators SV Partners says it has removed directors John Few and Gaohua (Wilson) Min “to the extent they had been validly appointed”.

Biotech Daily cannot find an announcement of Mr Min’s appointment as a director of Epsilon.

Last year, Epsilon founder (then The Hydroponics Co) and deputy chair Alan Beasley requisitioned an extraordinary general meeting to replace director Stuart Cameron and chair Xiao (Josh) Cui, citing “the governance of the board” (BD: Nov 21, 2023).

In December, Mr Cui called an extraordinary general meeting to remove Mr Beasley and appointed John Few as a director (BD: Dec 4, 2023).

Soon after, SV Partners said it had been appointed as Epsilon’s administrators following a resolution by the company’s directors, to assess its “business operations and financial affairs”, and the company was suspended from quotation by the ASX (BD: Dec 18, 2023).

Epsilon was in a suspension and last traded at 2.4 cents.