Biotech Daily

Wednesday March 31, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ACTINOGEN UP 15%; USCOM DOWN 6%**

*** PHARMAXIS, PROF FIONA WOOD TRIAL PXS-6302 FOR SCAR INHIBITION**

*** OPTHEA: FDA OPT-302 FOR WET AMD PAEDIATRIC WAIVER**

*** CELLMID RIGHTS RAISE $4.5m**

*** MEDIBIO 'OVER-SUBSCRIBED' PLAN RAISES $1m; TOTAL $4m**

*** TELIX APPOINTS GRAND RIVER ILLUCCIX (TLX591-CDx) MANUFACTURER**

*** MEMPHASYS TESTS FELIX ENGINEERING FIX**

*** PARADIGM, BENE AGREE NEW PPS INDICATIONS**

*** INVEX, FDA MEETING FOR PHASE III PRESENDIN IIH TRIAL**

*** US PATENT FOR PATRYS DEOXYMAB COMBINATION FOR CANCER**

*** CRESO PAYS $70k FOR MUSHROOM PSILOCYBIN EXTRACTION**

*** PHARMAUST MONEPANTEL DOG CANCER TRIAL UNDERWAY**

*** PHILLIP INCREASES, DILUTED TO 19.6% OF ADHERIUM**

*** SUMMATIX DILUTED BELOW 5% IN ADHERIUM**

*** MEDLAB LOSES CFO, CO SEC ALAN DWORKIN; 4 APPOINTMENTS**

*** ANTEOTECH APPOINTS CFO GAIL JUKES**

*** NEUROSCIENTIFIC APPOINTS DOUGAL THRING, DR ALEXANDRA HEATON**

MARKET REPORT

The Australian stock market was up 0.78 percent on Wednesday March 31, 2021, with the ASX200 up 52.3 points to 6,790.7 points. Nineteen of the Biotech Daily Top 40 stocks were up, 14 fell and seven traded unchanged. All three Big Caps were up.

Actinogen was the best, up 0.5 cents or 14.7 percent to 3.9 cents, with 13.1 million shares traded. Opthea and Prescient climbed 10 percent or more; Patrys was up 7.4 percent; Immutep improved 6.6 percent; Compumedics and Osprey were up more than five percent; Amplia, Cynata and Impedimed improved four percent or more; Alterity and Proteomics were up more than three percent; Cyclopharm, Orthocell and Resonance rose two percent or more; Neuren and Pharmaxis were up more than one percent; with Clinuvel, Cochlear, CSL, Mesoblast and Resmed up by less than one percent.

Uscom led the falls, down one cent or 5.7 percent to 16.5 cents, with 263,555 shares traded. LBT and Optiscan fell more than four percent; Genetic Signatures was down 3.1 percent; Starpharma and Universal Biosensors shed more than two percent; Avita, Nanosonics, Oncosil, Paradigm, Polynovo and Telix were down more than one percent; with Pro Medicus and Volpara down by less than one percent.

PHARMAXIS

Pharmaxis says it is planning a safety and tolerability trial of topical cream PXS-6302 for the inhibition of scar tissue formation, working with Prof Fiona Wood.

Pharmaxis said the trial would be undertaken by a group of researchers at the University of Western Australia and Perth's Fiona Stanley Hospital, led by Prof Fiona Wood, the founder and co-inventor of Avita's Recell 'spray-on skin' burn treatment technology.

The company said PXS-6302 had "shown promising pre-clinical results in inhibiting the enzymes that play a critical role in the development of scar tissue … [and had] potential to transform trauma recovery by blocking the underlying fibrosis causing scar tissue".

Pharmaxis said the trial would determine the safety and tolerability of the product in healthy volunteers, which would lead to further trials in burns and surgical patients.

The University of Western Australia's Dr Kylie Sandy-Hodgetts said that "current treatments aim to rectify the scar in the acute phase such as during wound healing and scar maturation through options such as compression therapy, silicone gel sheeting or when the scar is established by cryotherapy, scar revision or laser with limited outcomes."

"[PXS-6302] may potentially avoid the need for invasive procedures such as further surgery or laser procedures," Dr Sandy-Hodgetts said.

Prof Wood said it was "exciting for the research team to explore a novel path to reduce scarring and to be moving closer to that goal".

"Scar-less healing is the vision that has motivated our work over many decades," Prof Wood said.

Pharmaxis was up 0.1 cents or 1.25 percent to 8.1 cents with 1.7 million shares traded.

OPTHEA

Opthea says it has an initial paediatric study plan waiver from the US Food and Drug Administration for its OPT-302 for wet age-related macular degeneration (AMD).

Opthea said an initial paediatric study plan detailed the strategy for investigation of the new medicinal product in patients younger than 18 years and was required for drug marketing applications, with the FDA able to issue waivers for certain conditions.

The company said the waiver for OPT-302 in the wet AMD paediatric population meant that it would not have to conduct an additional study in subjects less than 18 years old.

Opthea chief executive officer Dr Megan Baldwin said that "the agreed … waiver is an important regulatory milestone in the US that is required to be completed before Opthea is able to submit a marketing application for OPT-302 to the FDA".

"Opthea will continue the process to further fulfilling regulatory requirements by focusing on our pivotal phase III clinical trials in adult patients that are designed to support potential marketing approval of OPT-302 for the treatment of wet AMD," Dr Baldwin said.

Opthea was up 15.5 cents or 10.8 percent to $1.585 with 1.65 million shares traded.

CELLMID

Cellmid says its 7.5 cents rights issue has raised $4,516,369 of a hoped-for $3.8 million.

Cellmid said it raised $3,816,369, with lead manager and underwriter, Mahe Capital Pty Ltd agreeing to place an additional $700,000.

The company said that the offer included one option for every two shares purchased, exercisable at cents by 18 cents by April 1, 2023.

Earlier this month, Cellmid said that the offer price was a 26 percent discount to the 30-day volume-weighted average price (BD: Mar 8, 2021).

Cellmid was up 0.6 cents or 7.1 percent to nine cents.

MEDIBIO

Medibio says it has raised $1,000,000 of a hoped-for $500,000 in an over-subscribed share plan at 0.9 cents a share, taking the total raised to $4,000,000.
Last month, Medibio said it had raised $3.0 million in a placement at 0.9 cents a share (BD: Feb 10, 2021).
Today, the company said it had received applications for $1.54 million worth of shares, which had been scaled-back, and investors would receive one free attaching option for every four shares purchased, exercisable at 1.5 cents each by February 24, 2024.
The company said CPS Capital Group was the lead manager to the capital raising.
Medibio was up 0.1 cents or 12.5 percent to 0.9 cents with 17.7 million shares traded.

TELIX PHARMACEUTICALS

Telix says the Grand Rapids, Michigan-based Grand River Aseptic Manufacturing will manufacture its Illuccix for prostate cancer imaging for commercial distribution.
Telix said Grand River would provide “advanced aseptic fill and finish” services for Illuccix, formerly TLX591-CDx kit for preparation of its 68-gallium-prostate-specific membrane antigen 11 (Ga-PSMA-11), for sale in the US, Canada, Europe and Australia.
Telix Americas president Dr Bernard Lambert said that “with commercial distribution agreements in place with major radio-pharmacy networks covering over 90 percent of the US population, we are pleased to have entered this agreement with [Grand River Aseptic Manufacturing], thus delivering a key component of our manufacturing and supply chain strategy for [good manufacturing practice] manufacturing of Telix’s first commercial product”.
Telix fell five cents or 1.15 percent to $4.28 with 742,392 shares traded.

MEMPHASYS

Memphasys says it has identified and is assessing a resolution method to fix an engineering flaw found in its Felix sperm separation device.
Earlier this month, Memphasys said it had found an engineering flaw in the device during validation, which would delay production and sales (BD: Mar 8, 2021).
Today, the company that the modification did not require “a major redesign of the device” and most of the verification processes so far would not be affected by the modification.
Memphasys said the final version of the device would need extra time for retooling and manufacture, but preliminary internal assessments had resolved the issue.
Memphasys was up 0.35 cents or 5.4 percent to 6.85 cents with 1.9 million shares traded.

PARADIGM BIOPHARMA

Paradigm says it will collaborate with Bene Pharmachem to develop pentosan poly-sulphate sodium (PPS) to address “unmet needs in new clinical indications”.
Last year, Paradigm said the Geretsried, Germany-based Bene would supply its injectable pentosan poly-sulphate sodium for several indications for 25 years (BD: Sep 29, 2020).
Today, the company said collaboration agreement aimed to further “the understanding of the chemical, scientific, and clinical attributes of PPS”.
Paradigm said both parties would fund the research and development costs and had established a committee to attribute intellectual property ownership, with Paradigm responsible for the commercialization of any resulting intellectual property.
Paradigm fell four cents or 1.5 percent to $2.57 with 690,210 shares traded.

INVEX THERAPEUTICS

Invex says it has requested a meeting with the US Food and Drug Administration for its phase III trial of Presendin for idiopathic intracranial hypertension.
Invex said it was seeking further protocol assistance on the proposed endpoints of its trial of Presendin, or Exenatide, versus placebo for idiopathic intracranial hypertension (IIH), which included the number of headache days per month and intracranial pressure monitoring.
The company said that to request the meeting it had filed a pre-investigational new drug (IND) application a proposed study protocol and statistical analysis plan.
Invex chair Dr Jason Loveridge said that the request was “an important milestone for the company”.
“The feedback sought from the FDA will be an important consideration as the company contemplates the filing of an IND following the official minutes of the meeting, expected [by October 2021],” Dr Jason Loveridge said.
Invex was up one cent or 1.3 percent to 79.5 cents.

PATRYS

Patrys says the US Patent and Trademark Office has granted a patent for its deoxymabs in combination with radio-sensitizing agents for multiple cancers.
Patrys said the patent, titled ‘Cell-penetrating anti-DNA antibodies and uses thereof inhibit DNA repair’, would protect the combination of its deoxymabs, including both PAT-DX1 and PAT-DX3, with radio-sensitizing agents that damaged DNA or inhibited DNA repair, such as cisplatin and doxorubicin, until August 2033.
The company it had a total of six patents across the US, Europe, Japan and China.
Patrys was up 0.2 cents or 7.4 percent to 2.9 cents with 18.3 million shares traded.

CRESO PHARMA

Creso says it will pay Advanced Extraction Systems Inc about $70,000 for a carbon dioxide “super-critical extraction system” for psilocybin mushroom extracts.
Earlier this month, Creso said it would acquire the Windsor, Nova Scotia-based Halucenex Life Sciences for its psychedelic drug program and planned to begin an up-to 20 patient phase II trial of the mushroom-derived psilocybin for post-traumatic stress disorder in June 2021 (BD: Mar 15, 2021).
Today, the company said the extraction system would take the Charlottetown, Prince Edward Island-based Advanced Extraction Systems up-to eight weeks to design and install at Halucenex’s laboratory.
Creso said the supercritical extraction system would produce consistent, high quality psychedelic extracts from psilocybin mushrooms.
The company said Halucenex would explore psilocybin efficacy, potential faster onset, and effective dosing for the trial and future research.
Creso said that Halucenex had applied for a dealer’s licence from Health Canada which it would amend to allow for the production of botanical psychedelic extracts from psilocybin mushrooms.
The company said the dealer’s licence was expected “imminently, with the licence amendment expected to be received within 45 days after the grant of the dealer’s license”.
Creso was unchanged at 20 cents with 36.3 million shares traded.

PHARMAUST

Pharmaust says six dogs, of an undisclosed number, with stage 4 to 5 B-cell lymphoma have completed assessment across five participating trial sites.

In February, Pharmaust said it had begun recruitment of 'several' dogs in its second trial of monepantel for naïve B cell lymphoma (BD: Feb 15, 2021).

Last year, Pharmaust said that monepantel for naïve B cell lymphoma in dogs was successful, with one of seven dogs having a 60 percent reduction in tumor size after treatment (BD: May 12, 2020).

Today, the company said one dog was not in compliance with the dosing instructions of treatment with monepantel after food, and that dog was withdrawn from the trial.

Pharmaust said that "some mild and occasional inappetence was reported in some dogs but this appears insignificant and difficult to attribute solely to [monepantel]".

In 2014, The company began its first trial of the Elanco sheep round worm treatment, then known as PPL-1, but the dogs found the tablets unpalatable (BD: Sep 9, 2014).

Pharmaust employed several companies to reformulate the tablets to make them palatable (BD: Jul 11, 2016: Jun 27, 2017).

The company said that side-effect levels to date were below those of other conventional anti-cancer drugs and trial veterinarians report that, at day-28, all participating dogs had been "in good spirits and well within themselves" and the owners elected to continue treatment on compassionate use.

Pharmaust said that a further six dogs that did not meet the trial criteria were being treated under compassionate use in combination with other anti-cancer drugs.

The company said it would perform an analysis of monepantel and monepantel sulfone blood levels achieved in the trial, to "provide a conservative baseline threshold for the very satisfactory side-effect profile observed".

Pharmaust chief scientific officer Dr Richard Mollard commented said it was "very satisfying to see minimal side effects after the observed inappetence during the first trial with the tablets".

Pharmaust was up half a cent or five percent to 10.5 cents.

ADHERIUM

Phillip Asset Management says it has increased but been diluted in Adherium from 104,261,036 shares (25.07%) to 166,666,667 shares (19.62%).

The Melbourne-based Phillip Asset Management said it was acting as the trustee for the Bioscience Managers Translation Find 1.

Earlier this month, Adherium said it had commitments to raise $18 million at 1.5 cents a share (BD: Mar 18, 2021).

Adherium was unchanged at 1.6 cents.

ADHERIUM

Melbourne's Summatix Pty Ltd says its holding in Adherium has been diluted below substantial following a capital raising (see above).

Last year, Summatix said it held 35,496,341 shares (5.90%) and Biotech Daily calculates that Summatix has been diluted to 4.18 percent (BD: June 9, 2020).

MEDLAB CLINICAL

Medlab said it has appointed Simon Allsop as interim chief financial officer and Drew Townsend as company secretary to replace Alan Dworkin, effective on April 1, 2021.
Medlab said it had appointed Robert Jansen as US medical science liaison and Naresh Patel as business development manager.
The company said Mr Dworkin would resign after six years as chief financial officer and it had begun the search for a permanent chief financial officer with healthcare experience.
Medlab said Mr Allsop was the founder of Ikeep Bookkeeping Pty Ltd and had previously worked for KPMG.
The company said Mr Jensen was a pharmacist had previously worked for the US-based CVS Pharmacy, and would aim to advance compassionate access to Nanabis in the US.
Medlab said that Mr Patel had previously worked for Clarity Global Group which specialized in commercial activities, logistics and marketing.
Medlab fell half a cent or two percent to 24 cents.

ANTEOTECH

Anteotech says it has appointed Gail Jukes as chief financial officer effective from July 1, 2021.
Anteotech said Ms Jukes had more than 20 years' experience as a finance executive and had previously worked for Kestrel Coal and F L Smidth.
Anteotech was up one cent or 4.2 percent to 25 cents with 2.9 million shares traded.

NEUROSCIENTIFIC

Neuroscientific says it had appointed Dougal Thring as head of clinical development and Dr Alexandra Heaton as director of operations.
Neuroscientific said that Mr Thring and Dr Heaton would provide support for its "the upcoming clinical programs in glaucoma and neurodegenerative diseases".
The company said Mr Thring had more than 12 years' experience in clinical development and had previously worked for Linear Clinical Research.
Neuroscientific said Mr Thring held a Bachelor of Medical and Pharmaceutical Biotechnology from the University of South Australia and a Master of Pharmaceutical Medicine from the University of New South Wales.
The company said Dr Heaton had previously worked for Linear Clinical Research and held a Doctor of Philosophy in Neuroscience from the University of Western Australia.
Neuroscientific fell half a cent or 1.9 percent to 26 cents.