# Biotech Daily

Thursday February 2, 2023

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECH UP: NEXT SCIENCE UP 7%; GENETIC SIGNATURES DOWN 5%**

*** ALLEGRA REVENUE FALL, POSSIBLE IP SALE, FUNDING, R&D**

*** CLINUVEL: 'AFAMELANOTIDE REDUCES UV DAMAGE, BACKS DNA REPAIR'**

*** IMUGENE TAKES TUMOR TRIAL TO VAXINIA, KEYTRUDA COMBINATION**

*** HONG KONG ISSUES RECCE TRADEMARK**

*** PYC FILES VP-001 IND TO FDA**

*** NEUROSCIENTIFIC RECEIVES $3.8m FEDERAL R&D TAX INCENTIVE**

*** ANTERIS REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** DOLBY INCREASES, DILUTED, TRANSFERS 15% OF COGSTATE**

*** NOMINATE BIO-MELBOURNE WOMEN IN LEADERSHIP AWARDS**

## MARKET REPORT

The Australian stock market was up 0.13 percent on Thursday February 2, 2023, with the ASX200 up 9.9 points to 7,511.6 points. Twenty of the Biotech Daily Top 40 stocks were up, 13 fell, six traded unchanged and one was untraded.

Yesterday's 11.4 percent worst, Next Science, was today's best, up four cents or 7.3 percent to 58.5 cents, with 99,506 shares traded. Cyclopharm and Uscom climbed more than six percent; Kazia, Neuren, Polynovo, Proteomics and Volpara improved four percent or more; Micro-X, Nanosonics, Opthea and Patrys were up more than three percent; Cochlear, Paradigm and Pro Medicus rose more than two percent; Atomo, Clinuvel, CSL and Orthocell were up more than one percent; with Avita, Medical Developments and Telix up by less than one percent.

Genetic Signatures led the falls, down four cents or 4.65 percent to 82 cents, with 17,401 shares traded; followed by Amplia down 4.4 percent to 8.6 cents with 32,000 shares traded. Alcidion, Impedimed and Nova Eye were down more than three percent; Cynata shed 2.9 percent; Actinogen, Antisense, Immutep, Mesoblast and Pharmaxis were down one percent or more; with Emvision, Resmed and Starpharma down by less than one percent.

## ALLEGRA ORTHOPAEDICS

Allegra says revenue for the six months to December 31, 2022 is down 7.4 percent, it may have to sell some of its intellectual property but its Sr-HT-gahnite is “on-track”.
Allegra said the Covid-19 pandemic continued to negatively impact revenues but it expected revenue for the six months to June 30, 2023 to return to pre Covid-19 levels, with “strong case bookings for February 2023 already in hand”.
The company said that it was “exploring a wide range of opportunities to raise capital to enable it to fast-track [its Sr-HT-gahnite cervical spinal cage] commercialization project.
Allegra said that “such opportunities may include the sale of certain intellectual property rights, or divestment of part of the intellectual property, including registered patents and application for patents, held in relation to the bio ceramic material Sr-HT-Gahnite”.
The company said its plan to submit its Sr-HT-gahnite cervical spinal cage to the US Food and Drug Administration for 510(k) approval “around March 31, 2023 … [was] on-track”.
In 2014, the then Advanced Surgical Design and Manufacture said it had licenced the Sr-HT-gahnite composite bio-compatible ceramic material from the University of Sydney for veterinary and orthopaedic indications (BD: Apr 2, 2014).
Advanced Surgical chief executive officer Tom Milicevic said at that time that “in preliminary studies, Sr-HT-gahnite has duplicated the mechanical strength, elasticity and bioactivity of bone … [and was] 100 times mechanically stronger than synthetic bone substitute materials in clinical use”.
In 2016, Allegra said that University of Sydney professor of bio-medical engineering Prof Hala Zreiqat and her team used three-dimensional printing technology to developed the ceramic, composed of strontium, hardystonite (a calcium-zinc-silicate) and gahnite (a zin-caluminium-oxide), described as Sr-HT-gahnite (BD: Jun 8, 2016).
Allegra was untraded at eight cents.

## CLINUVEL PHARMACEUTICALS

Clinuvel says its nine-patient trial of afamelanotide shows it reduces skin damage, ultra-violet light-erythema response, increases pigmentation and supports DNA repair.
Last year, Clinuvel said it dosed the first of up-to 10-healthy adults in a mechanistic study of 16mg afamelanotide for DNA repair (BD: Feb 14, 2022).
Clinuvel at the time said the CUV151 study, would evaluate the oxidative damage caused by ultra-violet (UV) radiation and focus on the potency of the drug in reduction, and extent of regeneration, of cellular DNA damage.
The company said the trial would assess afamelanotide on UV-induced DNA-damage repair capacity in healthy volunteers with fair skin types.
Today, Clinuvel said the trial showed afamelanotide was well tolerated, but two patients reported headaches and one had “mild nausea”.
The company said the results found pre-afamelanotide skin had mean value of 3.55 redness and post-afamelanotide skin had mean value of 2.74 redness which led to reduced DNA damage incurred by UV-dose, and skin melanin density increased.
Clinuvel said that the study showed that afamelanotide “statistically decreases UV-erythema dose response ($p = 0.018$) … and increases skin pigmentation ($p < 0.05$)”.
“The observed decrease of the UV dose-response indicates the reduction of DNA damage incurred following afamelanotide treatment,” the company said.
Clinuvel head of clinical operations Dr Pilar Bilbao said “the analyses from healthy humans [indicates] the peptide’s beneficial effects in reducing UV-erythema dose response, an objective sign of DNA-damage caused by solar exposure”.
Clinuvel was up 44 cents or 1.8 percent to $24.57 with 150,142 shares traded.

## IMUGENE

Imugene says its phase I metastatic advanced solid tumors (Mast) study of CF33- hNIS, or Vaxinia, is ready for combination with pembrolizumab.

Imugene said that both of the second cohorts of the intravenous and intra-tumoral arms of the monotherapy trial had been completed, showing acceptable safety, allowing progress to the combination dose and a higher dose of the Vaxinia as a monotherapy.

The company said that trial began with a low dose of Vaxinia to patients with metastatic or advanced solid tumors who had at least two prior lines of standard-of-care treatment.

Imugene said the oncolytic virus had been shown “to shrink colon, lung, breast, ovarian and pancreatic cancer tumors in pre-clinical laboratory and animal models”.

The company said that the patients treated to date in the monotherapy group had the lowest doses of Vaxinia and showed acceptable safety, allowing new participants to receive it in combination with the immunotherapy pembrolizumab, marketed as Keytruda.

Last year Imugene says it had dosed the first of 100 patients in its phase I trial of its CF33-hNIS, or Vaxinia, oncolytic virotherapy for advanced solid tumors (BD: May 18, 2022).

Today, Imugene managing-director Leslie Chong said that “early data arising from our patients dosed at low levels with our CF33 oncolytic virus have indicated immune activation is occurring in the tumor microenvironment, turning the tumor from ‘immunologically cold to hot’”.

“This is a perfect time to introduce an immune checkpoint inhibitor such as pembrolizumab,” Ms Chong said.

Imugene was unchanged at 14 cents with 31.9 million shares traded.

## RECCE PHARMACEUTICALS

Recce says it has been issued a trademark covering its “antibiotics, antibiotics for human use [and] pharmaceutical preparations, namely mixed antibiotic preparations”.

The company said the trademark was issued by the Trade Marks Registry Intellectual Property Department in Hong Kong.

Recce said the trademark “strengthens the company’s intellectual property portfolio with those already registered in the biggest pharmaceutical markets in the world such as Australia, US, Europe, Japan and China”.

Recce was up half a cent or 0.8 percent to 64.5 cents.

## PYC THERAPEUTICS

PYC says it has filed an investigational new drug application to the US Food and Drug Administration for VP-001 for retinitis pigmentosa type 11.

PYC fell 0.2 cents or 2.9 percent to 6.6 cents with 3.3 million shares traded.

## NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says it has received $3,774,137 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Neuroscientific said the rebate related to research and development expenditure for its drug candidate Emtinb for the year to June 30, 2022.

Neuroscientific was up 0.1 cents or one percent to 9.9 cents.

## ANTERIS TECHNOLOGIES

Anteris has requested a trading halt “pending an announcement in relation to a proposed capital raising”.
Trading will resume on February 6, 2023 or on an earlier announcement.
Anteris was up eight cents or 0.3 percent to $26.20.

## COGSTATE

The Dagmar Dolby Trust says it has increased its holding in Cogstate but been diluted, and has transferred its shares to the Dagmar Dolby Fund.
Dagmar Dolby as trustee for the Dagmar Dolby Trust, said it increased and was diluted in Cogstate from 21,391,389 shares (15.06%) to 25,732,802 shares (14.84%).
Ms Dolby said the Trust acquired 2,139,139 shares for $577,568 or 27 cents a share on November 15, 2019 in a rights offer and a further 2,202,274 shares for $4,272,412 or $1.94 a share on January 31, 2023.
The Dagmar Dolby Fund said that on January 31, 2023 it became a substantial shareholder in Cogstate with 25,732,802 shares (14.84%).
Cogstate fell 11 cents or 5.5 percent to $1.88.

## BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says that nominations for the 2023 Women in Leadership Awards will close on February 15, 2023.
The Network said that the awards honor and profile women who were “driving change and impact in the health sciences industry”.
The Bio-Melbourne Network said the women were “innovators and leaders in their fields of expertise, make outstanding contributions and serve as role models and mentors”.
The Network said that there were three award categories, recognizing emerging leaders, inspiring leaders and distinguished leaders.
For more information and to nomination candidates, go to: https://bit.ly/3JHkWcq.