



Biotech Daily

Monday September 5, 2022

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: ANTISENSE UP 7%; DIMERIX DOWN 10%**
- * **OCCURX RAISES \$16m FOR OCX-063 INFLAMMATION, FIBROSIS TRIAL**
- * **ASX INDICES: INCANNEX, NEUREN UP; CLINUVEL, STARPHARMA DOWN**
- * **MELBOURNE UNI, UWA LAUNCH CLINICAL ENTREPRENEUR PROGRAM**
- * **CLARITY CU-64 SAR-BOMBESIN PROSTATE CANCER IMAGING TRIAL**
- * **CLINUVEL APPLIES TO EU FOR SCENESSE FOR ADOLESCENT EPP**
- * **TOTAL BRAIN: SONDERMIND ACQUISITION AGM**
- * **CRESO LENDS TARGET HEALTH HOUSE \$700k**
- * **US PATENT FOR TISSUE REPAIR GLUCOPRIME FOR SKIN CONDITIONS**
- * **NUHEARA TAKES 'CAPITAL RAISING' HALT TO SUSPENSION**
- * **PERENNIAL VALUE REDUCES TO 13.9% OF MICROBA**
- * **WEISS, BROOKDALE TAKE 5.2% OF RESAPP**
- * **RECCE APPOINTS CHAIR DR JOHN PRENDERGAST EXECUTIVE**

MARKET REPORT

The Australian stock market was up 0.34 percent on Monday September 5, with the ASX200 up 23.5 points to 6,852.2 points. Ten of the Biotech Daily Top 40 stocks were up, 23 fell, six traded unchanged and one was untraded. All three Big Caps fell.

Antisense was the best, up 0.7 cents or 7.1 percent to 10.5 cents, with 924,703 shares traded. Neuren climbed 5.9 percent; Alcidion and Polynovo were up more than three percent; Clinuvel and Nova Eye rose two percent or more; with Avita, Emvision, Next Science and Opthea up by less than one percent.

Dimerix led the falls, down 1.5 cents or 9.7 percent to 14 cents, with 242,720 shares traded; followed by Amplia down 9.1 percent to 10 cents, with 161,808 shares traded. Imugene lost 8.2 percent; Oncosil and Resonance fell more than seven percent; Volpara lost 6.9 percent; Starpharma was down 5.6 percent; Kazia and Patrys fell four percent or more; Cyclopharm and Micro-X were down more than three percent; Actinogen and Prescient shed more than two percent; Genetic Signatures, Immutep, Impedimed, Mesoblast, Paradigm, Proteomics, Resmed and Telix were down more than one percent; with Cochlear, CSL, Medical Developments, Nanosonics and Pro Medicus down by less than one percent.

[OCCURX, BRANDON CAPITAL, UNISEED](#)

Occurx says it has raised \$16 million from Brandon Biocatalyst, Uniseed to progress clinical trials for its OCX-063 oral therapy for inflammation and fibrosis.

The Melbourne-based Occurx said the \$16 million included a \$1.5 million grant from the Brandon Capital biomedical incubator, Cureator.

The company said the funding would allow it to progress its chronic kidney disease clinical program for the lead compound OCX-063, following a phase I clinical trial in healthy volunteers.

Occurx executive chair Prof Darren Kelly said the company was progressing its clinical development program to patients with chronic kidney disease.

“Our aim is to develop an oral therapy to treat and prevent fibrosis that often leads to disease progression and organ failure,” Prof Kelly said.

Occurx said that it had appointed Dr Gareth Lewis as chief commercial officer and Dr Michelle Bradney as chief operating officer.

The company said it had “a platform of candidate drugs and validated the role of a novel receptor which mediates signalling pathways associated with inflammation and fibrosis”, with potential for fibrotic diseases including those impacting the kidney, lung, eye and skin. Occurx is a private company.

[STANDARD & POOR'S DOW JONES INDICES](#)

Standard & Poor's says Incannex and Neuren have been promoted into the ASX300, with Clinuvel and Starpharma removed from the ASX200 and ASX300, respectively.

Standard & Poor's said the changes would be effective from September 19, 2022.

Previously, Standard & Poor's has told Biotech Daily that inclusion in the indices is based solely on market capitalization.

The Biotech Daily Top 40 Index (BDI-40) is based on quality of science, benefit to human health, board and management, investment potential and market capitalization.

[AUSTRALIAN CLINICAL ENTREPRENEUR PROGRAM, MTP CONNECT UNIVERSITY OF MELBOURNE, UNIVERSITY OF WESTERN AUSTRALIA,](#)

The University of Melbourne says with the University of Western Australia it has launched a clinical entrepreneur program to “advance clinician-led innovation”.

In a media release, the Australian Clinical Entrepreneur Program (Auscep) said it was funded through MTP Connect's \$32 million Researcher Exchange and Development within Industry initiative, and was inspired by the UK National Health Service's clinical entrepreneur program.

Auscep said it aimed “to accelerate ideas that have the potential to change healthcare for the benefit of patients, staff and the broader health system in any area such as digital health, medical devices, service delivery improvements, new ground-breaking treatments or diagnostics”.

Auscep said the two-year pilot program would be run in Victoria, New South Wales and Western Australia, to develop clinician's personal and commercial skills, as well as test and scale their ideas.

Auscep chief clinical entrepreneur Dr Brandon Carp said that clinicians were “uniquely placed to identify problems, see opportunities” and understand how best to navigate the health system to develop responses.

“Auscep will upskill clinicians through an eight pit stop program that includes defining the problem, refining the solution, building a team and raising capital,” Dr Carp said.

CLARITY PHARMACEUTICALS

Clarity says it has opened recruitment for its 50-patient, phase II, 64-copper sarcophagine (SAR)-bombesin for prostate cancer imaging trial.

In June, Clarity said the US Food and Drug Administration had approved its investigational new drug application for SAR-bombesin, allowing it to proceed with its 'Sabre' 50-patient, single-arm, open-label, US 64-SAR-bombesin positron emission tomography (PET) imaging trial in patients with prostate-specific membrane antigen (PSMA)-negative biochemical recurrence of prostate cancer following definitive therapy (BD: Jun 6, 2022).

Today, the company said the primary objective was "to investigate safety and tolerability of the product as well as its ability to correctly detect recurrence of prostate cancer".

Clarity executive chair Dr Alan Taylor said that subject to the outcomes of the trial, "we will look to progress this diagnostic product into phase III trials in the US as soon as possible".

"We are also preparing a submission to the US FDA for an investigational new drug application for a therapeutic clinical trial with the product later this year," Dr Taylor said.

Clarity was up 3.5 cents or 5.5 percent to 67 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says it has applied to the European Medicines Agency to expand the Scenesse label for erythropoietic protoporphyria to include adolescent patients.

Clinuvel said Scenesse, or afamelanotide 16mg, was the only approved therapy for the prevention of phototoxicity in adult patients with erythropoietic protoporphyria (EPP), and that about 21 percent of patients with EPP were younger than 18 years old.

The company said that the submission for approval for adolescent patients aged 12 to 17 years of age followed the treatment of the first adolescent patients in the European Union, and that Scenesse was well-tolerated.

Clinuvel said the earliest approval of the expansion of its label would be December 2022.

Clinuvel chief scientific officer Dr Dennis Wright said "having gained experience with the treatment of EPP patients over the past sixteen years, including those under real-world conditions, we have confidence in the safety profile of Scenesse".

"With experience gained from the recent treatment of adolescent patients, we believe the clinical benefit-risk assessment for use in this patient population supports the widening of the approved indication," Dr Wright said.

"Having worked closely with the EPP community – patients, their families, and expert physicians – for nearly two decades, we are excited at the prospect of facilitating treatment for a larger group of patients, particularly knowing the severe impact EPP has during the development stages of adolescents, who are forced to live in isolation," Dr Wright said.

Clinuvel was up 42 cents or 2.2 percent to \$19.67 with 118,606 shares traded.

TOTAL BRAIN

Total Brain says an extraordinary general meeting will vote on the proposed acquisition of Sondermind Health for \$US10 million (\$A14.4 million) on October 19, 2022.

Last month, Total Brain said the Denver, Colorado-based telehealth company Sondermind would buy it, pending shareholder approval (BD: Aug 5, 2022).

Today, the company said that directors "unanimously recommend" that all shareholders vote in favor of the acquisition, with directors, comprising about 13 percent of shares, intended to vote in favor of the acquisition.

Total Brain was untraded at 3.9 cents.

CRESO PHARMA

Creso says it will loan target acquisition medical marijuana distributor Health House International \$700,000 for “general corporate purposes and working capital”.

Creso said Health House would use the loan to complete a scheme implementation deed and report for its acquisition for up to \$4,630,388 in shares and options (BD: Aug 1, 2022).

The company said it had provided \$500,000 to Health House under the loan facility, at 12 percent interest a year, and that the repayment date would be November 30, 2022.

Creso said its loan would rank second to the security held by Zelira Therapeutics.

In June, Zelira said it had terminated its proposal to acquire Health House and that Health House would have to pay it \$50,000 immediately, as well as repay its \$1.5 million working capital facility loan, plus interest, within 60 days from that date (BD: Jun 22, 2022).

Creso fell 0.2 cents or 5.1 percent to 3.7 cents with 1.25 million shares traded.

TISSUE REPAIR

Tissue Repair says the US Patent and Trademark Office has allowed its patent for Glucoprime for “topically applied methods of treating any skin condition”.

Tissue Repair told Biotech Daily the patent, titled ‘Isolated Biological Polysaccharide Compound, Methods of Use and Methods of Manufacture’, should protect its intellectual property until July 30, 2041 but might be extended.

Tissue Repair co-founder Tony Charara said the patent was “significant as it provides broad protection for the use of our proprietary Glucoprime technology across its current dual focus of chronic wounds and post procedure cosmetic healing, as well as extending protection into any topically applied skin condition, such as pressure ulcers, diabetic foot ulcers, surgical wounds and burns”.

Tissue Repair was up two cents or 6.45 percent to 33 cents.

NUHEARA

Nuheara has requested a voluntary suspension following its trading halt pending the “release of an announcement regarding a potential capital raising” (BD: Sep 1, 2022).

Trading will resume on September 8, 2022 or on an earlier announcement.

Nuheara last traded at 24 cents.

MICROBA LIFE SCIENCES

Sydney’s Perennial Value Management says it has reduced its substantial holding in Microba from 40,898,790 shares (14.91%) to 38,064,790 shares (13.87%).

Perennial said it bought and sold shares between August 22 and September 2, 2022, with the single largest sale of 1,000,000 shares for \$209,538 or 20.95 cents a share.

Microba was unchanged at 21 cents.

RESAPP HEALTH

Weiss Asset Management, and its associates, says they have become substantial in Resapp with 44,518,133 shares or 5.18 percent.

The Boston-based Weiss said that, with Brookdale International Partners and Andrew Weiss, it bought shares between August 15 and September 2, 2022, at prices ranging from 18.50 cents to 19.96 cents.

Resapp was unchanged at 20 cents with 29.25 million shares traded.

[RECCE PHARMACEUTICALS](#)

Recce says it has appointed non-executive chair Dr John Prendergast as executive chair, effective immediately.

Recce said the US-based Dr Prendergast was appointed as a non-executive director in April 2018, before becoming non-executive chair in July 2019.

The company said Dr Prendergast would receive a yearly salary of \$US250,000 (\$A368,868) plus superannuation and performance-based bonuses.

Recce fell 3.5 cents or 4.4 percent to 76.5 cents.