



Biotech Daily

Monday April 22, 2024

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: IMUGENE UP 20%; CLARITY DOWN 5%**
- * **GENETIC SIGNATURES: TGA OKAYS EASYSscreen 'FLU KIT REDESIGN**
- * **ACTINOGEN ENROLS PHASE IIa XANAMEM DEPRESSION TRIAL**
- * **PYC: 'PYC-003 SAFE IN MONKEYS, HUMAN KIDNEY TRIAL 2025**
- * **AUSTCO REQUESTS 'PLACEMENT, RIGHTS ISSUE' TRADING HALT**
- * **VITURA REQUESTS 'CONTRACT LEGAL PROCEEDINGS' TRADING HALT**
- * **TELEX \$2m CEO PERFORMANCE RIGHTS, 93% DIRECTOR FEE HIKE AGM**
- * **RTL TAKES 12.5% OF ANATARA**
- * **KRISTY JO, ROB MCGRORY REPLACE COCHLEAR CO-SEC RAY JARMAN**
- * **CLINUVEL APPOINTS DR EMILIE RODENBURGER, MYLES CLOUSTON**
- * **VITURA LOSES FOUNDING CEO RODNEY COCKS; TOM HOWITT INTERIM**

MARKET REPORT

The Australian stock market was up 1.08 percent on Monday April 22, 2024, with the ASX200 up 81.9 points to 7,649.2 points. Nineteen of the Biotech Daily Top 40 stocks were up, 13 fell and eight traded unchanged.

Friday's nine percent worst, Imugene, was today's best, up 1.4 cents or 19.7 percent to 8.5 cents, with 62.3 million shares traded. Syntara climbed 13.3 percent; Amplia was up 6.6 percent; Nanosonics and Percheron improved more than four percent; Actinogen, Mesoblast and Telex were up more than three percent; Alcidion, Cochlear, CSL, Curvebeam and Nova Eye rose two percent or more; Dimerix, Neuren, Opthea, Polynovo, Pro Medicus, Proteomics, Resmed and SDI were up one percent or more, with Emvision up by 0.9 percent.

Clarity led the falls, down 13 cents or 4.8 percent to \$2.60, with 1.1 million shares traded. Atomo, Compumedics, Impedimed and Medical Developments lost more than three percent; Genetic Signatures, Next Science and Resonance shed more than two percent; Micro-X and Orthocell were down more than one percent; with 4D Medical, Avita and Clinuvel down by less than one percent.

GENETIC SIGNATURES

Genetic Signatures says the Therapeutics Good Administration has reviewed and approved its redesigned Easyscreen respiratory pathogen detection kit in Australia. Last year, Genetic Signatures said its Easyscreen respiratory pathogen detection kit was not consistently detecting influenza B “in a small portion of low viral concentration samples” (BD: Aug 25, 2023).

Today, the company said that the updated kit had “minor modifications to the assay design which improved the detection of influenza B in samples with low concentration of the virus”.

Genetic Signatures said following the accepted review it would begin selling the kit as the Australian influenza season commenced, with the modifications also cleared in the UK and European Union.

Genetic Signatures chief executive officer John Melki said the company was “delighted to have secured TGA authorization for sales of our modified Easyscreen respiratory detection kit in time for the upcoming Australian influenza season”.

“While this process did have a material impact on our sales revenue during the 2023 influenza season, we have maintained strong relationships with our customers throughout this time,” Mr Melki said.

“We fully expect that the modified 3-base assay for influenza B will enable them to adopt our Easyscreen respiratory detection kit in line with their usage in previous influenza seasons,” Mr Melki said.

Genetic Signatures fell 1.5 cents or 2.2 percent to 67.5 cents.

ACTINOGEN MEDICAL

Actinogen says it has enrolled all 167 cognitive impairment patients in its randomized, placebo-controlled, phase IIa trial of Xanamem for major depressive disorder.

In 2022, Actinogen said it had treated the first of 160-patients in the trial of its oral, cortisol synthesis inhibitor, Xanamem, for major depressive disorder (BD: Dec 8, 2022).

Today, the company said results were expected by October 2024, after all patients had completed six weeks of treatment with 10mgXanamem, or placebo, and four weeks of follow-up.

Actinogen said cognitive impairment, or “‘foggy thinking’ is reported by the majority of patients with major depressive disorder and may not respond to traditional anti-depressant therapy”.

Actinogen chief medical officer Dr Dana Hilt said the company was “pleased to announce the final patient has enrolled in our Xanacidd phase IIa clinical trial in patients with cognitive impairment in major depressive disorder”.

“This robust, placebo-controlled trial of 167 people will inform us if Xanamem can improve cognition in these patients and assess any related effects on symptoms of depression itself,” Dr Hilt said.

“Any positive effects on cognition in this trial would confirm prior trial findings of cognitive enhancement and support the likelihood of future success in the on-going, 36-week, phase IIb ... trial in patients with Alzheimer’s disease,” Dr Hilt said.

“We continue to observe the excellent safety profile for Xanamem and believe its low drug-to-drug interaction potential makes it an ideal candidate for use in multiple diseases and populations,” Dr Hilt said.

Actinogen was up 0.1 cents or 3.45 percent to three cents with 2.9 million shares traded.

PYC THERAPEUTICS

PYC says it has completed dose range finding studies of PYC-003 for kidney disease in monkeys, with human trials expected to begin by 2025.

PYC said eight non-human primates in four cohorts received PYC-003 at 3mg/kg, 10mg/kg and 30mg/kg doses, with no treatment-related adverse events reported.

The company said that polycystic kidney disease was a monogenic disease that caused large numbers of cysts to form in the kidneys and that monogenic indications had “the highest likelihood of success in clinical development”.

PYC said it was “on track” to file regulatory submissions for human trials by January 2025, and, if successful, to have initial in-human data “in 2025”.

PYC chief executive officer Dr Rohan Hockings said the study was “very encouraging” and expected that the human therapeutic dose was about “one-tenth of the highest dose administered in these studies based on the data that we have generated to date”.

“If we can repeat these [non-human primate] results in the ... toxicology studies, we expect to have a very substantial safety margin for PYC-003,” Dr Hockings said. “This raises the possibility of observing an efficacy signal very early on in clinical development as we expect even the lower doses administered in the planned single ascending dose study could be within the therapeutic range in patients with [polycystic kidney disease].”

PYC fell 0.1 cents or 1.1 percent to nine cents with 6.65 million shares traded.

AUSTCO HEALTHCARE

Austco has requested a trading halt pending the “finalization of an announcement regarding a placement and rights issue”.

Trading will resume on April 24, 2024, or on an earlier announcement.

Austco last traded at 19.5 cents.

VITURA HEALTH

Vitura has requested a trading halt pending an announcement “in respect of certain legal proceedings relating to a material contract”.

Trading will resume on April 24, 2024, or on an earlier announcement.

Vitura last traded at 16 cents.

TELIX PHARMACEUTICALS

Telix says investors will vote to issue managing-director Dr Chris Behrenbruch 144,037 performance rights and increase the director fee pool 92.85 percent to \$1,350,000.

Telix said Dr Behrenbruch’s 144,037 performance rights, worth about \$2 million, would be in addition to his \$570,780 yearly salary and up-to \$371,007 short-term incentive and would be subject to performance milestones, marketing authorization submission for its prostate cancer therapy and interim data from a phase III renal cancer trial.

Telix said shareholders would vote to increase the director fee pool from an aggregate \$700,000 to \$1,350,000, with yearly director pay increasing from \$86,000 to \$115,000 and annual chair salary increasing from \$170,000 to \$230,000.

The company said the meeting would vote to adopt the remuneration report, re-elect director Dr Andreas Kluge and approve amendments to its equity incentive plan.

The meeting will be held online and in-person at the Wesley Conference Centre, Lyceum Room, 220 Pitt Street, Sydney, on May 22, 2024 at 10am (AEST).

Telix was up 49 cents or 3.6 percent to \$14.10 with 1.1 million shares traded.

[ANATARA LIFESCIENCES](#)

RTL Group Investments Pty Ltd says it has increased its substantial shareholding in Anantara from 12,542,857 shares (10.46%) to 21,000,000 shares (12.50%).

The Sydney-based RTL said that on December 18, 2023 it bought 5,017,143 shares for \$110,377 or 2.2 cents a share, in an entitlement offer, and on March 5, 2024 it bought 3,440,000 on market for \$119,387, or an average of 3.47 cents a share.

Last year, Anantara said its non-renounceable entitlement offer at 2.2 cents a share raised \$1,055,344 (BD: Nov 3, Dec 7, Dec 18, 2023).

Anantara was up 0.3 cents or 7.7 percent to 4.2 cents with 1.2 million shares traded.

[COCHLEAR](#)

Cochlear says it has appointed Kristy Jo and Rob McGrory as joint company secretaries to replace retiring company secretary Ray Jarman, effective from today.

Cochlear was up \$7.40 or 2.3 percent to \$323.05 with 86,495 shares traded.

[CLINUVEL PHARMACEUTICALS](#)

Clinuvel says it has appointed Dr Emilie Rodenburger as head of clinical affairs and Myles Clouston as head of US investor relations.

Clinuvel said Dr Rodenburger had worked at the company for more than a decade in clinical development roles in Australia, the US and Europe, leading its first vitiligo trials and helping complete the erythropoietic protoporphyria program, resulting in the successful approval and commercialization of Scenesse.

The company said Dr Rodenburger would be UK-based and oversee its clinical programs, evaluating melanocortin-based drugs for skin and brain disorders and completing the clinical development of Scenesse for vitiligo.

Clinuvel said New York's Mr Clouston would focus on increasing its profile and had worked for the Nasdaq's advisory leadership team as well as with Xilio Therapeutics, Morphosys and Mylan.

Clinuvel fell 13 cents or 4.8 percent to \$2.60 with 1.1 million shares traded.

[VITURA HEALTH](#)

Vitura says founding chief executive officer Rodney Cocks will resign on June 30, 2024, with chief financial officer Tom Howitt appointed interim chief executive officer.

Vitura said Mr Cocks was a co-founder of the company and had been chief executive officer for about six years, including delivering its initial public offering and its acquisitions of CDA Health and Doctors on Demand.

The company said it had begun a chief executive officer recruitment process, with financial controller Ben Cirillo appointed interim chief financial officer during the transition period.

Vitura chair Robert Iervasi thanked Mr Cocks "for his contribution and commitment to the company over the last six years".