



# Biotech Daily

Thursday September 24, 2020

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: PATRYS UP 7%; ANTISENSE DOWN 9%**
- \* **TELIX FILES US NDA FOR TLX591-CDx**
- \* **CHIMERIC \$4.3m BAKER YOUNG CONVERTIBLE NOTE**
- \* **INCANNEX READY FOR PHASE IIb IHL-42X MARIJUANA APNOEA TRIAL**
- \* **OSPREY: REGIONAL HEALTH CARE AUSTRALIA, NZ DISTRIBUTOR**
- \* **CARDIEX, MOBVOI PARTNER FOR HEART HEALTH SMARTWATCH**
- \* **CYNATA: STEM CELLS REGENERATE CARDIAC BLOOD VESSELS IN RATS**
- \* **BIONOMICS \$2.2m 1-FOR-12.54 RIGHTS OFFER; TRADING HALT**
- \* **AZURE: CANADA PATENT FOR TRANSMUCOSAL TOCOTRIENOLS**
- \* **PHARMAUST, LEIDEN UNI TEST MONEPANTEL FOR SARS-COV-2, EX-VIVO**
- \* **INVITROCUE J-V COMPLETES ACE-2 LAB MICE FOR COVID-19 TESTING**
- \* **LIFESPOT REQUESTS 'PLACEMENT' TRADING HALT**
- \* **JOHN MCBAIN, PICTON, 52nd CELEBRATION TAKE 11% OF RHINOMED**
- \* **DRS WASHER INCREASE, DILUTED TO 23% IN EMERALD**
- \* **BIONOMICS LOSES PETER TURNER; GAINS DR SRINIVAS RAO, DR JANE RYAN**

## MARKET REPORT

The Australian stock market fell 0.81 percent on Thursday September 24, 2020, with the ASX200 down 48.0 points to 5,875.9 points. Seven of the Biotech Daily Top 40 stocks were up, 29 fell, three traded unchanged and one was untraded. All three Big Caps fell.

Patrys was the best, up 0.1 cents or 7.1 percent to 1.5 cents, with 17.7 million shares traded. Imugene improved 4.4 percent; Genetic Signatures and Prescient were up more than three percent; Orthocell rose 2.5 percent; with Starpharma and Telix up by less than one percent.

Antisense led the falls, down one cent or 8.7 percent to 10.5 cents, with 945,444 shares traded. Amplia and Avita lost more than seven percent; Uscom shed 5.6 percent; Alterity, Clinuvel, Cyclopharm, Dimerix, Nanosonics, Next Science, Oncosil, Osprey and Paradigm fell four percent or more; Actinogen, LBT, Medical Developments, Mesoblast, Proteomics and Resonance were down three percent or more; Immutep, Kazia, Nova, Opthea, Polynovo and Volpara shed two percent or more; Cynata, Impedimed, Pro Medicus and Resmed were down more than one percent; with Cochlear, CSL and Neuren down by less than one percent.

## TELIX PHARMACEUTICALS

Telix says it has filed a US Food and Drug Administration new drug application (NDA) for its TLX591-CDx for prostate cancer imaging.

Telix said TLX591-CDx, or 68-gallium-prostate-specific membrane antigen-11 (68-Ga-PSMA-11) used positron emission tomography for the imaging of prostate cancer.

The company said the submission included clinical data from more than 600 patients from both prospective and retrospective clinical studies, including data which showed that TLX591-CDx was superior to conventional imaging in men with newly diagnosed high-risk prostate cancer (BD: Jun 10, 2020).

Telix US head Dr Bernard Lambert said the company was pleased with the “significant milestone with the submission of the first commercial NDA for PSMA imaging in the US”. “Telix has engaged with the FDA since July 2019, with valuable guidance resulting in what we believe to be a comprehensive submission,” Dr Lambert said.

Telix chief executive officer Dr Christian Behrenbruch said the submission was “a major commercial inflection point for the company and follows our European submission earlier this year” (BD: May 1, 2020).

Telix chief business officer Dr David Cade told Biotech Daily the company expected the FDA approval by July 2021.

Telix was up 1.5 cents or 0.85 percent to \$1.775 with one million shares traded.

## CHIMERIC THERAPEUTICS

Chimeric says it has raised \$4.3 million through Baker Young’s exercise of a convertible note, and appointed Baker Young and Bell Potter Securities as advisors.

Chimeric said the funds would be used for its 20-patient, phase I trial of chlorotoxin chimeric antigen receptor T-cells for glioblastoma (BD: Sep 22, 2020).

Chimeric is a public unlisted company

## INCANNEX (FORMERLY IMPRESSION) HEALTHCARE

Incannex says it has ethics approval for its 48-patient, phase IIb trial of the marijuana-derived IHL-42X for obstructive sleep apnoea at Melbourne’s Alfred Hospital.

Incannex said the randomized, double-blind, placebo-controlled, dose-ranging, cross over design trial would assess the therapeutic benefit of IHL-42X at three different dose levels.

The company said patients would receive three different doses, as well as a placebo, over four one-week treatment periods, separated by one-week washout periods.

Incannex said that on the final night of each treatment period subjects would visit the sleep clinic at the Alfred Hospital to have their sleep assessed using overnight polysomnography to measure the Apnoea Hypopnoea Index (AHI).

The company said that surveys would be completed to monitor endpoints and blood samples would be collected to monitor the safety of IHL-42X.

Incannex said the primary endpoint of the trial was a reduction in Apnoea Hypopnoea Index, compared to baseline or pre-treatment levels.

The company said participants would be monitored for improvements in alertness, daytime sleepiness, mood, and quality of life.

Incannex said the secondary endpoint of the trial would assess whether the improvement in AHI from IHL-42X also reduced seizure frequency in patients with comorbid epilepsy and obstructive sleep apnoea.

Incannex said patient recruitment was expected to start “in the near future”.

Incannex was up 0.2 cents or 3.6 percent to 5.7 cents with 4.1 million shares traded.

## OSPREY MEDICAL INC

Osprey says it has appointed Regional Health Care Group to distribute its Dyevert cardiac contrast reduction technology in Australia and New Zealand.

Osprey said the three-year agreement with the Sydney-based Regional Health had “annual minimum sales volumes and a fixed transfer price over the term of the agreement” but did not disclose specific details.

The company said Dyevert reduced the amount of contrast dye required in heart procedures by an average 40 percent, addressing the problem of contrast-induced acute kidney injury following heart imaging procedures in patients with chronic kidney disease. Osprey fell 0.1 cents or 4.2 percent to 2.3 cents with 16.65 million shares traded.

## CARDIEX

Cardiex says it will partner with Beijing’s Mobvoi to produce smartwatches for heart health using its subsidiary Atcor Medical’s Sphygmocor blood pressure technology.

Cardiex said Mobvoi would develop the hardware and firmware for the smartwatch and Cardiex would integrate a specific algorithm based on Atcor’s Arty health analytics and features including Atcor’s Heart Stress, Arterial Age, Exercise Capacity, Arty Score and artificial intelligence-powered health coaching services.

The company said the smartwatch features would use Atcor’s Sphygmocor blood pressure monitor and photo-plethysmo-gram (PPG) optical sensor for remote diagnosis and monitoring of hypertension and cardiovascular disease.

Cardiex the smartwatch would be marketed with a subscription to Cardiex’s Health360 service, with revenue to be split with 60 percent to Cardiex and 40 percent to Mobvoi.

The company said it expected the smartwatch to be launched in North America by April 2021 for an initial six-month sales period, followed by two-year agreement for international sales with minimal sales quantities to be achieved by Mobvoi, unspecified royalty fees for each sale of the smartwatch to Cardiex, and the continuation of the subscription revenue split to Cardiex, pending a joint review by both companies.

Cardiex said that during initial launch it would have co-distribution rights in North America, Australia and New Zealand and during the full launch it would have international co-distribution rights with Mobvoi.

Cardiex was up 0.1 cents or two percent to five cents with 30.5 million shares traded.

## CYNATA THERAPEUTICS

Cynata says a study of 45 rats has shown that its Cymerus mesenchymal stem cells can generate new blood vessels for the recovery of blood supply after a heart attack.

Cynata said the study induced a myocardial infarction, or heart attack, in the rats, which then received either Cymerus mesenchymal stem cells, bone marrow-derived stem cells or a placebo for four days.

The company said its Cymerus stem cells enhanced the development of new blood capillaries by twice as much as the placebo group.

Cynata said its stem cells enhanced arteriogenesis, or the growth of arterioles, whereas bone marrow derived mesenchymal stem cells did not, and the Cymerus group had “nearly three times as many” arterioles compared to the placebo control.

The company said that the increased growth of blood vessels following treatment with Cymerus stem cells related to the release of “higher levels of molecules known to be involved in the stimulation of new blood vessel growth”.

Cynata fell 1.5 cents or 1.4 percent to \$1.025.

## BIONOMICS

Bionomics says it hopes to raise \$2,173,320 in a pro-rata, non-renounceable, one-for-12.54 entitlement offer at four cents a share.

Bionomics said the share price was 77.8 percent discount to the 18 cents last closing price and the same price as the placement to Malta's Apeiron Investment Group.

In June, Bionomics said Apeiron, the family office of Christian Angermayer, would subscribe for \$5,433,320 at four cents a share, pending shareholder approval and it would hold a rights offer at that price to raise up to \$15,000,000 (BD: Jun 2, Sep 23, 2020).

Today, the company said the record date for the retail offer was September 28, opening on October 1 and closing on October 15, 2020.

Bionomics said the funds for a phase II trial in post-traumatic stress disorder.

Separately, Bionomics said it had requested a trading halt until September 28, 2020 or an earlier announcement.

Bionomics last traded at 18 cents.

## AZURE HEALTH TECHNOLOGY (FORMERLY INVICTUS BIOPHARMA)

Azure says Canada has allowed a patent for the transmucosal delivery of tocotrienols.

Azure said the patent, titled 'Transmucosal delivery of tocotrienols' would provide intellectual property protection until 2033.

Azure chief executive officer Dr Glenn Tong said patents had been granted in the US, the European Union, Japan, Australia, New Zealand, Singapore and South Africa.

Azure is a public unlisted company

## PHARMAUST

Pharmaust says the Netherlands' Leiden University Medical Centre will test monepantel and monepantel sulfone for Sars-Cov-2, in ex-vivo models.

In June, Pharmaust said that the Walter and Eliza Hall Institute had confirmed the compounds, originally developed as sheep roundworm drench, and later by Pharmaust for cancer in humans and dogs, reduced severe acute respiratory syndrome-coronavirus-2 (Sars-Cov-2) infectivity in-vitro "by up-to ... 95 percent" (BD: Jun 18, 2020).

Today, the company said Leiden University would determine the applicability of the compounds for Sars-Cov-2 by testing them in ex-vivo human infection models replicating cultured human airway epithelial tissue.

Pharmaust said it would pay an unspecified fee to Lieden University and would own all intellectual property resulting from the study, with the studies to begin shortly and Leiden University to provide the final data report in December this year.

Pharmaust was unchanged at 12.5 cents with 1.4 million shares traded.

## INVITROCUE

Invitrocue says it has completed development of its Ace-2 Humanized Immune Mice, or Himice, platform for in-vivo testing against Sars-Cov-2 or Covid-19 in lab mice.

Last year, Invitrocue said it had a joint venture with Singapore's Dr Quingfeng Chen to provide humanized immune system mice and cell products for research, with Invitrocue holding 70 percent and Dr Chen having 30 percent of the joint venture (BD: Feb 11, 2019).

Today, the company said the Himice could be used for other viruses or diseases that target the angiotensin-converting enzyme 2 (ACE-2) receptor.

Invitrocue was in a suspension and last traded at six cents.

### LIFESPOT HEALTH

Lifespot has requested a trading halt “pending an announcement in relation to a proposed share placement to a strategic investor”.

Trading will resume on September 28, 2020 or on an earlier announcement.

Lifespot last traded up 0.5 cents or 11.4 percent to 4.9 cents.

### RHINOMED

Dr John McBain, Picton Cove and Fifty-Second Celebration say they have increased their Rhinomed holding from 11,638,566 shares (8.20%) to 28,179,516 shares (11.10%).

The Melbourne-based Dr McBain said he bought and sold shares between September 2019 and August 2020 but Biotech Daily quantities and prices were illegible.

Rhinomed was up half a cent or 3.3 percent to 15.5 cents.

### EMERALD CLINICS

Dr Stewart Washer and Dr Patrizia Washer say they have increased but been diluted in Emerald from 48,000,000 shares (26.1%) to 48,550,499 shares (22.9%).

The Perth-based Dr Stewart and Dr Patrizia Washer said that between March 6 and September 9, 2020 they bought 550,499 shares for \$46,250 or an average of 8.4 cents share, and were diluted on September 7, 2020 following a \$2.2 million placement at eight cents a share (BD: Aug 28, 2020).

Emerald was unchanged at 8.3 cents.

### BIONOMICS

Bionomics says it has appointed Apeiron Investment Group nominee Dr Srinivas Rao as a director with, Dr Jane Ryan replacing director Peter Turner.

Bionomics said Dr Rao was nominated as the second Apeiron director, along with Aaron Weaver, as part the Apeiron’s investment in the company (BD: Jul 3, 2020).

The company said Dr Rao had more than 19 years’ experience in the pharmaceutical and biotechnology industries and was currently Atai Life Sciences AG chief scientific officer.

Bionomics said Dr Rao held a Bachelor of Science from the New Haven, Connecticut-based Yale College, a Doctor of Medicine from the Yale School of Medicine, and a Doctor of Philosophy and Master of Science from Yale Graduate School.

The company said Dr Ryan, who would replace Mr Turner on the board, had more than 30 years’ experience in the pharmaceutical and biotechnology industries and was currently a non-executive director with Anatara Lifesciences.