



# Biotech Daily

Tuesday September 22, 2020

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: AMPLIA UP 9%; PROTEOMICS DOWN 8%**
- \* **ROCHE PAYS \$617m FOR QUEENSLAND UNI, DUBLIN INFLAZOME**
- \* **CHIMERIC, CITY OF HOPE CHLOROTOXIN CAR-T FOR GLIOBLASTOMA**
- \* **OPTISCAN \$9.8m PLACEMENT, \$7.4m FROM CLERMONT GROUP**
- \* **KAZIA, DANA-FARBER TRIAL PAXALISIB FOR CNS LYMPHOMA**
- \* **NEUREN MANUFACTURES NNZ-2591 FOR PHASE II TRIALS**
- \* **SUDA: DOG STUDY BACKS LOWER DOSE ANAGRELIDE**
- \* **LITTLE GREEN: CBD CONTENT BELOW TGA MINIMUM**
- \* **RESPIRI APPOINTS ENTECH WHEEZO MANUFACTURER**
- \* **G MEDICAL EGM VOTES TO DELIST, SUSPENDED FROM ASX**
- \* **CARDIEX REQUESTS 'MATERIAL COMMERCIALIZATION DEAL' HALT**
- \* **INCANNEX APPOINTS DR PAUL LIKNAITZKY SCIENTIFIC ADVISOR**

## MARKET REPORT

The Australian stock market fell 0.66 percent on Tuesday September 22, 2020, with the ASX200 down 38.5 points to 5,784.1 points. Eight of the Biotech Daily Top 40 stocks were up, 22 fell, nine traded unchanged and one was untraded. All three Big Caps were up.

Amplia was the best for the second day in a row, up 1.5 cents or 9.4 percent to 17.5 cents, with 595,684 shares traded. Cyclopharm climbed 5.9 percent; Nova Eye improved 4.55 percent; Resmed and Resonance rose more than three percent; Pro Medicus improved 2.4 percent; with Cochlear, CSL, Mesoblast, Nanosonics and Prescient up one percent or more.

Proteomics led the falls, down four cents or 7.7 percent to 48 cents, with 71,118 shares traded. Genetic Signatures lost 6.6 percent; Avita and Dimerix fell more than four percent; Impedimed, LBT, Opthea and Paradigm were down three percent or more; Clinuvel, Compumedics, Cynata, Immutep, Imugene, Starpharma and Uscom shed two percent or more; Kazia, Medical Developments, Next Science, Universal Biosensors and Volpara lost one percent or more; with Polynovo and Telix down by less than one percent.

## UNIVERSITY OF QUEENSLAND

The University of Queensland says the Basel, Switzerland-based Roche has paid EUR380 million (\$A617 million) for Inflazome, co-owned with Trinity College Dublin. The University of Queensland said it would receive additional payments based on the achievement of milestones and Roche would have full rights to its portfolio of “inflammasome” inhibitors.

The University said the Dublin-based Inflazome was founded in 2016 and two of Inflazome’s drug candidates were in trials for unnamed conditions, but provided no further information.

Inflazome’s website said it was developing orally available NLRP3 inflammasome inhibitors to address “a wide variety of inflammatory diseases”.

The [www.clinicaltrials.gov](http://www.clinicaltrials.gov) website said that Inflazome had completed phase I safety and pharmacokinetic trials of IZD334 and Inzomelid for cryopyrin-associated periodic syndromes and had planned a six-patient phase I trial of IZD174 for Parkinson’s disease.

## CHIMERIC THERAPEUTICS

Chimeric says it has licenced chlorotoxin chimeric antigen receptor T-cells from California’s City of Hope and has begun an about 20-patient trial for glioblastoma.

The Sydney-based Chimeric said that the chlorotoxin chimeric antigen receptor T-cells used a peptide derived from scorpion toxin to direct T-cells to target glioblastoma in a phase I trial at City of Hope, with the first patient recently starting treatment.

The company said it had the rights to develop and commercialize the chlorotoxin chimeric antigen receptor T-cells, as well as further develop the therapy for other cancers.

Chimeric executive chairman Paul Hopper said the licence was “an exceedingly rare opportunity to acquire a promising phase I technology in one of the most exciting areas of immuno-oncology”.

“Furthermore, the ... therapy has completed years of pre-clinical research and development, and recently enrolled its first patient in a phase I clinical trial for brain cancer,” Mr Hopper said.

Chimeric said that chimeric antigen receptor T-cells (Car-T) used a patient’s own re-engineered T-cells, which carried chimeric antigen receptors, to target cancer cells.

The company said that the chlorotoxin and chimeric antigen receptor T-cell combination was developed by the City of Hope’s Dr Christine Brown and colleagues and showed “potent anti-tumor activity against glioblastoma ... in pre-clinical models”.

Chimeric said that chimeric antigen receptors “commonly incorporate a monoclonal antibody sequence in their targeting domain, enabling Car-T cells to recognize antigens and kill tumor cells”.

The company said that, in contrast, its chlorotoxin chimeric antigen receptor T-cells used a synthetic 36-amino acid peptide sequence first isolated from death stalker scorpion venom and now engineered to serve as the recognition domain.

Chimeric said that City of Hope researchers used tumor cells in resection samples from a cohort of patients with glioblastoma to compare chlorotoxin binding with expression of antigens under investigation as Car-T cell targets and found that chlorotoxin bound to a greater proportion of patient tumors, and cells, within these tumors.

The company said that chlorotoxin binding included the glioblastoma stem-like cells thought to seed tumor recurrence and consistent with those observations, chlorotoxin Car-T cells recognized and killed broad populations of glioblastoma cells while ignoring non-tumor cells in the brain and other organs.

Chimeric is a public unlisted company.

### OPTISCAN IMAGING

Optiscan says it hopes to raise up to \$9,813,499 through a placement at 8.25 cents a share, with Singapore's Clermont Group taking \$7,382,513 as a cornerstone investor. Optiscan said that as part of the placement, it had a binding subscription agreement with Orchid, a member of the Clermont Group, to apply for 15 percent of total issued shares in the company, giving Clermont the right to appoint a non-executive director, subject to maintaining a 10 percent interest in Optiscan.

The company said the placement would include a free attaching option for every four placement shares, exercisable at 15 cents each within 30 months of the issue date. Optiscan said the funds would be used for the purchase and building of inventory, third party testing for regulatory purposes, for product research and development, to fund potential clinical trials, market development, recruitment and for working capital. Optiscan was in a trading halt and last traded at 10.5 cents.

### KAZIA THERAPEUTICS

Kazia says it has a collaboration with Boston's Dana-Farber Cancer Institute for a 25-patient, phase II trial of paxalisib for primary central nervous system lymphoma.

Kazia said the open-label, 25-patient trial of paxalisib, formerly GDC-0084, in patients with relapsed or refractory primary central nervous system lymphoma (PCNSL), was expected to take up to two years to complete.

The company said the primary endpoint would be to assess efficacy through overall response rate, measuring the ability of paxalisib to shrink tumors, with safety and other efficacy endpoints also measured.

Kazia said it would support the trial through an undisclosed financial grant and would begin recruitment by July 2021.

Kazia chief executive officer Dr James Garner said the collaboration was "an exciting new opportunity for the paxalisib program".

"We are delighted to support the team at Dana-Farber to explore the potential for paxalisib to benefit patients with PCNSL," Dr Garner said.

"Dana-Farber is one of the world's leading centres of excellence in this disease, so we are immensely fortunate to be working with them," Dr Garner said.

"We are pleased also to see a new and important target added to the broader paxalisib clinical program, and we look forward to seeing the project commence," Dr Garner said.

Kazia fell 1.5 cents or 1.6 percent to 93 cents.

### NEUREN PHARMACEUTICALS

Neuren says it has begun manufacturing NNZ-2591 for phase II clinical trials for Phelan-McDermid syndrome, Angelman syndrome and Pitt Hopkins syndrome in 2021.

In May, Neuren said it had begun its first phase I, 30-patient clinical trial of NNZ-2591 in healthy Australian adults to assess safety, tolerability and pharmacokinetics, following orphan drug designation by the US Food and Drug Administration for all three syndromes (BD: Oct 11, 16, 2019; May 7, 2020).

Today, the company said that the unnamed contract manufacturer that supplied the drug substance for its ongoing phase I trial would carry out the larger manufacturing for the phase II trials.

Neuren was unchanged at \$1.17.

## SUDA PHARMACEUTICALS

Suda says a dog study of anagrelide oral spray for cancer shows that a lower dose can be used to reduce exposure to the cardio-stimulatory metabolite, 3-hydroxy anagrelide.

Suda said the study compared three formulations of anagrelide, SS-101, EF-164 and EF-169, to the commercial capsule Xagrid and found that SS-101 increased exposure to cardio-stimulatory metabolite by 28 percent and statistically significantly increased bioavailability by 43 percent.

The company said it would continue to optimize the SS-101 formulation to ensure its stability and to produce a pharmaceutical grade product before pre-clinical toxicology studies and clinical trials.

Suda fell 0.2 cents or 4.4 percent to 4.3 cents.

## LITTLE GREEN PHARMA

Little Green says a post-market test of marijuana products has found the cannabidiol content of its Classic 20:5 was 1.7 percent below the minimum requirement.

Little Green said that given its use and reliance on an Australian Therapeutic Goods Administration (TGA)-accredited laboratory for testing, it was disappointed with the divergence in test results and would test its medicines at another laboratory until relevant testing alignment had been completed.

The company said it did not expect a financial impact from the result as it would continue to sell the product, the product batch had already been dispensed and it was not required to be recalled.

Little Green Pharma was unchanged at 28 cents.

## RESPIRI

Respiri says it has appointed the Adelaide-based Entech Electronics as the manufacturer of its Wheezo device for asthma.

Respiri said manufacturing would be conducted at Entech's Shenzhen, China-based operations and it had begun production preparation activities.

The company said the first orders had been placed, with 12,000 additional devices commissioned for delivery from February 2021.

Respiri said the partnership would reduce the cost of goods by 85 percent and was forecast to fall further.

Respiri was up one cent or 4.55 percent to 23 cents with 2.2 million shares traded.

## G MEDICAL INNOVATIONS HOLDINGS

G Medical says investors have voted to delist from the ASX, it has been suspended by the ASX from the close of trading yesterday and it expects to delist in October.

In 2017, G Medical said it raised \$12 million in its initial public offering at 20 cents a share to commercialize its mobile telephone electronic health devices (BD: May 10, 2017).

Earlier this month, the company said the ASX had formally confirmed that it would be removed from listing, subject to shareholder approval, on or about October 21, 2020 and provided details of the share disposal process (BD: Sep 2, 2020).

G Medical last traded at 3.9 cents.

## CARDIEX

Cardiex has requested a trading halt “pending an announcement regarding the company’s imminent signing of a material commercialization agreement”.

Trading will resume on September 24, 2020 or on an earlier announcement.

Cardiex last traded at 4.9 cents.

## INCANNEX HEALTHCARE

Incannex says it has appointed Dr Paul Liknaitzky as a scientific advisor, joining its medical advisory board for a minimum of 18 months.

Incannex said Dr Liknaitzky held academic research positions, including at Melbourne’s St Vincent’s Hospital, Deakin University and Odyssey House, and Sydney’s Macquarie University.

The company said that Dr Liknaitzky held a Bachelor of Science from the University of Western Australia and a Doctor of Philosophy from the University of Melbourne.

Incannex was up 0.1 cents or 1.9 percent to 5.3 cents with 3.7 million shares traded.