



# Biotech Daily

Tuesday March 24, 2020

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH UP: ALTERITY UP 42%; NEUREN DOWN 12%**
- \* **DOHERTY INSTITUTE JOINS COVID-19 TRIALS; PHARMALEX TRIAL LIST**
- \* **PARADIGM DOSES 10 US OSTEOARTHRITIS ACCESS PATIENTS**
- \* **CYCLOPHARM: 'COVID-19 BOOSTS TECHNEGAS USE'**
- \* **COMPUMEDICS WITHDRAWS GUIDANCE DUE TO COVID-19**
- \* **NEUREN: 'COVID-19 DEFERS TROFINETIDE RETT, NNZ-2591 TRIALS'**
- \* **HERAMED: 'COVID-19 INCREASES HERABEAT, HERACARE DEMAND'**
- \* **RESAPP, PHENIX TELE-HEALTH DEAL**
- \* **ELLEX EGM FOR \$100m LUMIBIRD SALE**
- \* **CELLMID 'POTENTIAL MATERIAL CONTRACT' VOLUNTARY SUSPENSION**
- \* **CRESO TO LAUNCH CANNAQIX MARIJUANA INSTANT TEA**
- \* **BOTANIX REQUESTS 'BTX1204 DERMATITIS RESULTS' TRADING HALT**
- \* **MGC EXTENDS MARIJUANA COVID-19 J-V SUSPENSION**
- \* **MORGAN STANLEY, MITSUBISHI TAKE 7% IN OPTHEA**

## MARKET REPORT

The Australian stock market was up 4.17 percent on Tuesday March 24, 2020, with the ASX200 up 189.7 points to 4,735.7 points. Twenty-seven of the Biotech Daily Top 40 stocks were up, nine fell and four traded unchanged. All three Big Caps were up.

Alterity was the best, up 0.5 cents or 41.7 percent to 1.7 cents, with 1.4 million shares traded. Paradigm climbed 35.3 percent; Ellex was up 24.7 percent; Amplia was up 23.9 percent; Cyclopharm and Uscom were up more than 21 percent; Medical Developments was up 17.35 percent; both Imugene and Proteomics rose 12.5 percent; Next Science, Opthea and Pharmaxis climbed more than 11 percent; both Antisense and Orthocell were up 10 percent; Patrys and Resmed were up more than nine percent; Oncosil, Prescient and Pro Medicus improved more than eight percent; Clinuvel and Polynovo were up more than seven percent; Nanosonics and Telis rose more than six percent; Cochlear and Immutep improved more than five percent; Cynata and Mesoblast were up four percent or more; Resonance and Volpara were up more than three percent; with CSL up 1.1 percent.

Neuren led the falls, down 13 cents or 11.7 percent to 98 cents, with 285,484 shares traded. Osprey lost 8.3 percent; Actinogen, Compumedics and Starpharma were down more than six percent; Dimerix and Impedimed fell four percent or more; Kazia shed 2.3 percent; with Genetic Signatures down 0.9 percent.

## [THE PETER DOHERTY INSTITUTE FOR INFECTION AND IMMUNITY, PHARMALEX](#)

The Peter Doherty Institute is planning trials of the anti-malarial drug hydroxy-chloroquine and the HIV treatment Kaletra for Covid-19 infection.

Biotech Daily has been able to confirm reports that the proposed trials were expected to begin “soon” in collaboration with the Royal Brisbane and Women’s Hospital, but no further details were available.

Overnight, the Friedrichsdorf, Germany-based advisory and compliance services company Pharmalex GmbH published a list of current and proposed trials.

Pharmalex said that Favilavi, which was the first approved coronavirus drug in China, has reportedly shown efficacy in treating Covid-19 safely in a clinical trial involving 70 patients. The company said that the first Covid-19 vaccine in China was expected to be ready for clinical trials by the end of April.

Inovio Pharmaceuticals plans to begin human clinical trials on their coronavirus vaccine INO-4800 in April this year with results expected in September 2020.

Pharmalex said Regeneron had accelerated its timeline for having doses of a potential vaccine (REGN3048 and REGN3051) and treatment ready for human clinical trials by early Northern Summer with manufacturing to start by the middle of April.

The company said that Gilead’s Remdesivir (GS-5734) was “an experimental broad spectrum anti-viral, originally designed to treat Ebola [and] has undergone clinical trials in China” on 761 patients in a randomized, placebo-controlled, double-blind study at multiple hospitals in Wuhan, with results expected “over the next few weeks”.

Pharmalex said Moderna’s mRNA-1273 vaccine, targeting the coronavirus Spike (S) protein, would be in a phase I study in April with support from the US National Institute of Health and a phase II study was being prepared.

The company said Roche’s Actemra had been approved in China for the treatment of severe complications related to coronavirus and was being evaluated in a China clinical trial expected to enrol 188 coronavirus patients.

Pharmalex said that “many” clinical trials were underway with chloroquine, which had been shown to be safe and efficacious against malaria.

The company said that coronavirus patients administered chloroquine phosphate “achieved a better drop in fever and shorter recovery time in clinical trials being conducted in Chinese hospitals” and large trials were “imminent”.

Pharmalex said an intranasal Covid-19 vaccine, similar to Nasovax, was being developed by the Gaithersburg, Maryland-based Altimmune with animal studies being progressed.

The company provided a table of 17 drug candidates from 16 companies for Covid-19 vaccines and treatments.

The list included Janssen Pharmaceuticals, Pfizer and Biontech, Vir Biotechnology with Wuxi and Alnylam, Generex, Takeda, Apeiron Biologics, Tonix Pharmaceuticals and Vaxart (formerly Aviragen and Australia’s Biota) with a candidate “to be confirmed”.

“As evident above, drug discovery and clinical research activities in Covid-19 prevention and treatment is increasing in pace,” Pharmalex said.

“It would not be surprising if a workable vaccine has already been discovered and is being tested at present,” the company said. “It will take some time to establish the complete safety and efficacy of the successful candidates but with the combined knowledge and urgency that now exists in [research and development], we should have reason to be confident of a future without Covid-19.”

“In the meantime, and unfortunately this may still be some months away, we must follow national health authority guidance, trust in science and stay safe for each other,”

Pharmalex said.

Biotech Daily agrees.

## PARADIGM BIOPHARMACEUTICALS

Paradigm says it has started dosing all 10 early-onset osteoarthritis patients in ITS US Food and Drug Administration Zolisul expanded access program.

Last month, Paradigm said it had dosed the first patient with Zolisul, or injectable pentosan polysulfate sodium, under the program (BD: Feb 18, 2020).

Today, the company said the first patient was expected to receive the final dose on March 23, 2020.

Paradigm said it had monitored the progression of each patient and noted "consistent positive feedback".

Paradigm chief executive officer Paul Rennie said that the patients' treatment had been "unaffected by the current Covid-19 pandemic".

Paradigm was up 42.5 cents or 35.3 percent to \$1.63 with 3.9 million shares traded.

## CYCLOPHARM

Cyclopharm says it has reports of increased use of Technegas to differentiate between Covid-19 and pulmonary embolism where laboratory tests results are not fast enough. Cyclopharm said that non-essential or outpatient imaging procedures were temporarily delayed and any delays in the use of Technegas in non-critical procedures were "short term and ... expected to rebound once gathering restrictions begin to lift".

The company said that the current primary diagnostic method for determining the presence of the Covid-19 virus was a laboratory test, but Technegas could be used to differentiate between Covid-19 and pulmonary embolism.

Cyclopharm managing-director James McBrayer told Biotech Daily that computed tomography (CT) scanning had increased with potential Covid-19 patients and was the first line of diagnosis for pulmonary embolism, with gamma camera or single-photon emission computed tomography (SPECT) camera diagnoses using Technegas, the second line.

Mr McBrayer said that the company had seen an increase in the use of inhaled Technegas which was safer for operators than the nebulized aerosol diethylene triamine penta-acetic acid (DTPA).

The company said its supply was uninterrupted with research and development "expected to be impacted as the rate of patient recruitment for trials is expected to slow or in some cases placed on hold during the outbreak".

Cyclopharm said it was ready to file its new drug application for Technegas to the US Food and Drug Administration "in the coming days" and a concurrent priority review application, if successful, the Prescription Drug User Fee Act (PDUFA) date would be reduced from 10 months to six months and a \$US2.9 million PDUFA fee waiver request was also submitted.

The company said that the US was the largest nuclear medicine market in the world and the size of the US market for Technegas was about \$US90 million in sales a year.

"We expect to gain a 50 percent share of this market in the first two to three years, rising to 80 percent over five to seven years," the company said.

Cyclopharm said it had lodged a statement of claim with the New South Wales Supreme Court to protect its intellectual property and seek damages from the defendants named in the matter, Bjorn Altmann and associated companies as David Rundell and associated companies.

Cyclopharm was up 16 cents or 21.6 percent to 90 cents.

## COMPUMEDICS

Compumedics says it has withdrawn its financial guidance for the year to June 30, 2020 and expects “adverse short-term impacts” due to Covid-19.

Compumedics said that containment measures in place to manage Covid-19 would “have some adverse impact on the performance of certain parts of the company’s business [and it was] developing and implementing contingency plans”.

Earlier this month, the company said it expected revenue of \$41 million and profit after tax of \$4 million, after six-month revenue to December 31, 2019 fell 2.1 percent to \$18,310,000, with net profit after tax down 80.1 percent to \$161,000 (BD: Mar 2, 2020).

Today, Compumedics said that up until this point it had been trading towards the market guidance and activity in China was starting to resume with new orders being received.

Compumedics executive chairman Dr David Burton said the management team had worked through previous “challenging market periods, including the Tech Crash in 2000, the 2001 9/11 crisis, the 2008 [Global Financial Crisis] and today we are more than ready to deal with and work through all the issues we are facing due to the Covid-19 pandemic”.

Compumedics fell two cents or 6.9 percent to 27 cents.

## NEUREN PHARMACEUTICALS

Neuren says that due to Covid-19 Acadia Pharmaceuticals has deferred patient enrolment in its trial for Rett syndrome and it has delayed its phase II NNZ-2591 trial

Last week, Neuren said the San Diego, California-based Acadia had made “excellent progress” in its 180-patient, phase III ‘Lavender’ trial of trofinetide in girls and young women, aged five to 20 years with Rett syndrome (BD: Oct 31, 2019; Mar 17, 2020).

Today, the company said Acadia would not enrol new patients due to the US measures to combat the Covid-19 pandemic, but the modification would not impact enrolled patients.

Neuren said it would delay plans for a phase II US trial of NNZ-2591 for Phelan-McDermid syndrome, which it had expected to begin “before the end of 2020” but the start and associated expenditure had been deferred, while non-clinical studies were on schedule.

Neuren fell 13 cents or 11.7 percent to 98 cents.

## HERAMED

Heramed says that due to the Covid-19 outbreak it has “received a significant uplift in interest and demand” for its in-home pregnancy monitoring products.

Heramed said the products included its Herabeat foetal heart rate monitor and its Heracare holistic pregnancy management digital platform.

The company said the Royal Australian and New Zealand College of Obstetricians and Gynaecologists had recommended that pregnant women reduce or postpone and shorten ante-natal visits, use telehealth consultations as a replacement or in addition to routine visits, limit hospital visitors and discharge from hospital early to avoid contracting coronavirus.

Heramed said it was responding to a the “significant increase in demand ... by optimizing its strategy and focusing on the most promising opportunities in order to satisfy demand and provide an effective telehealth solution”.

Heramed chief executive officer and co-founder David Groberman said the surge in demand for tele-health products had been “overwhelming”.

“This is where our in-home pregnancy management platform can make a significant difference while providing meaningful, genuine medical value,” Mr Groberman said.

Heramed was up 1.1 cents or 18.6 percent to seven cents.

## RESAPP HEALTH

Resapp says it will integrate its Resappdx-EU respiratory diagnostic into the Brisbane-based Phenix Health Pty Ltd's tele-health mobile telephone application.

Resapp said Resappdx-EU was "the only [product] for accurately diagnosing respiratory disease during a tele-health consultation that does not require additional hardware".

The company said the three-month joint development agreement with Phenix would integrate the two systems and the companies would negotiate the specifics of the fee-per-test payment model of using Resappdx-Eu on the Phenix application.

Phenix chief executive officer Dr Gillian Alexis said her company provided video consultations across Australia and since the beginning of the Covid-19 pandemic had seen "a 30 percent month-on-month increase in the number of consultations".

Resapp chief executive officer Dr Tony Keating said the Resappdx-EU would "provide tele-health clinicians with a remote testing capability to help manage the Covid-19 pandemic".

"[General practitioners] will be better able to determine whether a patient should attend hospital or clinic for additional care, conserving strained healthcare resources," he said. Resapp was up 7.6 cents or 110.1 percent to 14.5 cents with 22.5 million shares traded.

## ELLEX MEDICAL

Ellex says shareholders will vote on the proposed \$100 million sale of assets to Lumibird on Friday April 24, 2020.

Last year, Ellex said the Lannion, France-based Lumibird Group SA would pay \$100 million cash for its lasers and ultrasound business (BD: Nov 28, 2019; Jan 19, 2020).

Ellex said at that time that Lumibird would acquire its Tango and Tango reflex selective laser trabeculoplasty (SLT) lasers, the Ultra Q and Ultra Q Reflex lasers, Integre Pro and Integre Pro Scan lasers, the Eye Prime, Eye One and Eye Cubed ultrasound products and assume ownership of its Adelaide-based manufacturing facility.

Today, the company said that the independent expert Grant Thornton Corporate Finance Pty Ltd concluded the proposed transaction was fair and reasonable.

Ellex said the \$61 million proceeds would be distributed through a fully-franked dividend worth \$19.5 million, or 14 cents a share, and a return of capital of up to \$41.5 million or 29 cents a share, with \$21 million to be retained by the company, including \$2 million in escrow "to drive Itrack sales growth" and glaucoma consumable device acquisitions.

The company said that the balance of proceeds would meet the tax liability from the proposed transaction, closing adjustments and transaction costs.

Ellex said shareholders would vote to change the company's name to Nova Eye Medical and, subject to shareholder approval, the ASX has granted use of the ticker code EYE.

The meeting will be held at Ellex Medical Lasers, 3-4 Second Avenue, Mawson Lakes, South Australia on April 24, 2020 at 10am ACST, 10.30 am AEST.

Ellex said that shareholders were "strongly encouraged to vote by lodging a proxy form with the Ellex share registry" by 10am ACST (10.30am AEST) on April 22, 2020.

Ellex was up 12 cents or 24.7 percent to 60.5 cents.

## CELLMID

Cellmid has requested a voluntary suspension to follow the trading halt requested on March 20 pending "a potential material contract" (BD: Mar 20, 2020).

Trading will resume on March 27, 2020 or on an earlier announcement.

Cellmid last traded at 9.9 cents.

### CRESO PHARMA

Creso Pharma says it will add cannabidiol-based hemp tea to its marijuana-based Cannaqix product line for stress and mental functions by October 2020.

Creso said the Cannaqix cannabidiol (CBD) micro-granulated instant hemp tea was developed with the Lengnau, Switzerland-based Domaco Pharma and was designed to support the immune system

The company said the hemp tea was offered in two formulations: Cannaqix CBD instant hemp tea “to support the immune system and manage stress”; and Cannaqix Nite CBD instant hemp tea “to strengthen the immune system and support better sleep”.

Creso chief executive officer Dr Miri Halperin Wernli said there was “an increasing demand for easy-to-use natural products to help strengthen the immune system, particularly given the challenging healthcare times we are facing”.

Creso was up 0.4 cents or eight percent to 5.4 cents.

### BOTANIX PHARMACEUTICALS

Botanix has requested a trading halt pending “an announcement in relation to results of the BTX1204 phase II atopic dermatitis study”.

Trading will resume on March 26, 2020 or on an earlier announcement.

Botanix last traded at 6.7 cents.

### MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC has requested an extension to its voluntary suspension to follow the trading halt requested on March 19 for a Covid-19-related joint venture.

Last week, MGC requested a trading halt pending an announcement on “a material agreement regarding a strategic joint venture with a Swiss company in relation to Covid-19” (BD: Mar 19, 2020).

Yesterday, the company requested a voluntary suspension which it expected to last until March 24 (BD: Mar 23, 2020).

Today, MGC said it expected the suspension to last until March 25, 2020.

MGC last traded at 1.7 cents.

### OPTHEA

Morgan Stanley and its subsidiaries say they have become substantial in Opthea with 19,508,775 shares or 7.25 percent of the company.

The New York-based Morgan Stanley said it acquired the shares in more than 3,750 transactions, relating to a prime brokerage agreement, between November 20, 2019 and March 19, 2020, with the single largest purchase on January 9, 2020 of 21,126 shares for \$61,618 or \$2.92 a share, and the largest collateral amount received was 2,221,985 shares on January 28, 2020.

On March 25, Mitsubishi UFJ Financial filed a similar notice, saying it had more than a 20 percent interest in Morgan Stanley.

Opthea was up 15.5 cents or 11.1 percent to \$1.555 with 1.1 million shares traded.