



Biotech Daily

Tuesday March 23, 2021

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH UP: OPTISCAN UP 11%; OSPREY DOWN 5%**
- * **REDHILL OPAGANIB FOR SWISS COVID-19 'COMPASSIONATE USE'**
- * **RESPIRI: US FDA O-T-C APPROVAL FOR WHEEZO ASTHMA MONITOR**
- * **PHARMAUST'S EPICHEM, THERMAQUATICA WASTE-TO-FUEL DEAL**
- * **MGC CIMETRA (ARTEMIC) PHASE III COVID-19 TRIAL APPROVAL**
- * **CRESO US O-T-C LISTING; MORE PSILOCYBIN**
- * **TDM TAKES 24% OF SOMNOMED**
- * **THORNEY, TIGA INCREASE, DILUTED BELOW 5% OF LITTLE GREEN**
- * **BING-CHENG LIU REPLACES TBG DIRECTOR HIS-KAI WANG**

MARKET REPORT

The Australian stock market slipped 0.11 percent on Tuesday March 23, 2021, with the ASX200 down 7.1 points to 6,745.4 points. Twenty-one of the Biotech Daily Top 40 stocks were up, 14 fell and five traded unchanged.

Optiscan was the best, up 2.5 cents or 10.9 percent to 25.5 cents, with 956,385 shares traded. Actinogen and Impedimed climbed more than nine percent; Antisense and Compumedics were up more than seven percent; Prescient and Uscom rose more than six percent; Imugene and Telix improved more than four percent; Avita, Medical Developments and Resmed were up more than three percent; Clinuvel, Dimerix, Kazia, LBT and Resonance rose two percent or more; Cyclopharm and Mesoblast were up more than one percent; with CSL, Nanosonics, Paradigm and Volpara up less than one percent.

Osprey led the falls for the second day in a row, down 0.1 cents or 5.3 percent to 1.8 cents, with 6.5 million shares traded. Oncosil fell 4.1 percent; Starpharma was down 3.3 percent; Pharmaxis and Pro Medicus shed more than two percent; Cynata, Genetic Signatures, Immutep, Opthea, Orthocell and Polynovo were down more than one percent; with Cochlear, Neuren, Proteomics and Universal Biosensors down by less than one percent.

REDHILL BIOPHARMA

Redhill says it is acting on a request “to provide opaganib treatment ... under compassionate use exemption” for Swiss outpatients with Covid-19 pneumonia. Redhill said it had supplied the drug and treatment was begun with orally-administered opaganib in the past week.

The company said that opaganib was a novel, sphingosine kinase-2 inhibitor with dual anti-inflammatory and anti-viral activity, targeting a human cell component involved in viral replication and therefore expected to be effective against emerging viral variants with mutations in the spike protein.

Redhill chief operating officer Gilead Raday said the company “recently reported positive phase II data with opaganib in the US [and] our ongoing global 464-patient phase II/III study with opaganib for severe COVID-19 is now more than two thirds enrolled”.

The company said that the phase II/III randomized, double-blind, parallel-arm, placebo-controlled study of opaganib in patients with severe Covid-19 pneumonia requiring hospitalization and treatment with supplemental oxygen was being held at about 40 sites in eight countries.

Redhill said that the phase II study showed a greater improvement in reducing oxygen requirement by end of treatment on day-14, when opaganib was used with the standard-of-care, with no material safety differences between the opaganib and placebo arms.

In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).

On the Nasdaq, Redhill was up 16 US cents or 2.13 percent to \$US7.68 (\$A9.96) with 415,245 shares traded.

RESPIRI

Respiri says it has 510(k) clearance from the US Food and Drug Administration for its Wheezo asthma monitor and software application allowing US sales and marketing. Respiri said the Wheezo was intended to detect and record abnormal breath sounds at the trachea, or windpipe, for asthmatic patients.

The company, previously known as Karmelsonix and Isonex, has been developing the Wheezo asthma monitor since 2006 (BD: Nov 24, 2006).

Today, Respiri said the US Food and Drug Administration's 510(k) clearance permitted it to sell Wheezo as a class II medical device along with the Wheezo software application.

The company said that the initial target market would be asthmatic patients, in order to monitor wheeze severity and resolution, in collaboration with their treating doctor.

Respiri managing-director Marjan Mikel said the FDA clearance was “a highly significant and major milestone for the company as we continue to expand our regulatory footprint for Wheezo and enter substantial new markets”.

“The FDA is one of the most stringent regulatory bodies in the world and this clearance further validates the efficacy and utility of our Wheezo device and algorithm,” Mr Mikel said.

“To our knowledge [this is] the first time the FDA has cleared a device [or] mobile application for the detection, recording and changes of wheeze rates,” Mr Mikel said.

“This represents a step-change in technology for patients with respiratory wheeze seeking an effective, replicable and rapid device measurement and associated [software application] that monitors this important measurement of lung function,” Mr Mikel said.

Mr Mikel said the approval was as an over-the-counter device allowing sales with or without a prescription.

Respiri fell half a cent or 2.9 percent to 16.5 cents with 16.5 million shares traded.

PHARMAUST

Pharmaust says its wholly-owned subsidiary Epichem will develop waste to fuel technology with the Carbondale, Illinois-based Thermaquatica Inc.

Pharmaust said the agreement, through Epichem subsidiary Epichem OHD Pty Ltd, would use Thermaquatica's oxidative hydro-thermal dissolution (OHD) technology and combine it with biomass or feedstock "flow-reactor material science".

In January, the company said Western Australia had granted \$200,000 to its synthetic and medicinal chemistry subsidiary Epichem to convert electronic waste into useful end products (BD: Jan 22, 2021).

Today, Pharmaust said Epichem OHD would capitalize on recent Federal, state and local government policies to achieve zero organic waste to landfill.

The company said the benchtop flow-reactor under development would be "carbon neutral, environmentally sustainable and used oxygen and water at high temperature and pressure to break down input materials to form useful end products".

Pharmaust said the flow reactor technology was an invention of Thermaquatica founder and chief technology officer Ken Anderson, a US-based Australian and was under a licence agreement and patented intellectual property.

Epichem chief executive officer Colin La Galia said the flow reactor would make a "significant contribution in the capability to deal with waste and produce diesel, liquid fuels, biofuels, liquid fertilizers and bio-stimulants."

"The [oxidative hydro-thermal dissolution] technology will help support Australia's focus on sovereign capability to produce our own ethanol for our [personal protective equipment] requirements including the manufacture of hand sanitizer," Mr La Galia said. "It has the ability to support and sustain industries, ... be scaled up for a range of industry partners and create employment opportunities."

Pharmaust was up half a cent or five percent to 10.5 cents.

MGC PHARMA

MGC says it has ethics approval from two Israeli hospitals for its 252-patient, phase III trial of Cimetra, formerly Artemic, for Covid-19 patients expected to begin in April.

MGC said the ethics committee approval was from the Haifa-based Rambam Health Care campus and Nazareth-based Edinburgh Medical Missionary Society Nazareth Hospital. Last year, the company said its 50-patient phase II trial of Artemic for Covid-19 patients in Israel and India had "met the primary and secondary endpoints" (BD: Dec 15, 2020).

Today, MGC said the phase III placebo-controlled trial would evaluate the efficacy and safety of Cimetra on patients diagnosed with Covid-19.

The company said it had renamed Artemic as Cimetra as an investigational medicinal product and Artemic continued as a food supplement.

MGC was up 0.1 cents or 1.3 percent to 7.6 cents with 12.95 million shares traded.

CRESO PHARMA

Creso says it hopes to have its shares list on the US over-the-counter market and its target acquisition company Halucenex has acquired 700 mg of psilocybin.

Creso said the listing on the US Over The Counter Quality Exchange second board was due to "growing interest" from North American investors and would provide access to trade in the company's shares listed on the ASX in US dollars during US trading hours.

The company said it expected to list by July 2021 under the code CPH.

Creso was up two cents or 9.5 percent to 23 cents with 38.3 million shares traded.

SOMNOMED

TDM Growth Partners says it has increased its substantial shareholding in Somnomed from 18,863,038 shares (22.95%) to 19,934,291 shares (24.09%).

The Sydney-based TDM Growth Partners said on March 17, 2021 it bought 1,071,253 shares at \$1.90 a share.

TDM Growth Partners said the shares were held directly, by TDMAM Pty Ltd, Madleowill Investments Pty Ltd and Zoolander Investments Pty Ltd.

Somnomed was up 1.5 cents or 0.8 percent to \$1.945.

LITTLE GREEN PHARMA

Melbourne's Thorney, Thistle and Tiga Trading say they have increased and been diluted below substantial in Little Green.

In February, Little Green said it had "commitments" to raise \$22 million in a placement at 65 cents a share and hoped to raise \$5 million in a share plan (BD: Feb 9, 2021).

The Melbourne-based Tiga said between December 1, 2020 and March 12, 2021 it sold 352,386 shares at prices ranging from 60 cents to 87 cents, bought 1,900,837 shares in the placement and share plan and was diluted in the capital raising.

Biotech Daily calculates that Thorney and Tiga hold 9,207,461 shares or 4.92 percent of Little Green.

Little Green fell 4.5 cents or 5.8 percent to 72.5 cents with 1.05 million shares traded.

TBG DIAGNOSTICS

TBG says it has appointed Bing-Cheng Liu as a non-executive director, replacing Hsi-Kai Wang.

TBG said Mr Liu had more than 15 years' experience in corporate finance and investment evaluation, was currently the chief financial officer of 18.5 percent substantial shareholder Taiwan's Eternal Materials.

TBG said Mr Liu held a Master of Business Administration from the National Taiwan University.

TBG was in an ASX suspension and last traded at 27 cents.