

Biotech Daily

Wednesday March 16, 2022

Daily news on ASX-listed biotechnology companies

- * ASX UP, BIOTECH DOWN: ALCIDION UP 9%; MICRO-X DOWN 11%
- * HAEMOKINESIS \$17m IPO FOR RAPID BLOOD GROUP TESTS
- * VICTORIA \$10m FOR 20 CANCER RESEARCH PROJECTS
- * LBT SELLS FIRST 5 US APAS INSTRUMENTS; \$2m
- * REDHILL, KUKBO UP-TO \$10m SOUTH KOREA OPAGANIB COVID-19 DEAL
- * ENA DOSES 1st INNA-051 INFLUENZA CHALLENGE PARTICIPANTS
- * ALCIDION SIGNS \$1.9m MIYA DEAL WITH TAYSIDE NHS
- * CRESO TO SHIP 35k MARIJUANA LOZENGES TO SIERRA SAGE HERBS
- * REGAL REDUCES TO 6.5% OF ALTHEA
- * IMMURON APPOINTS PAUL BRENNAN DIRECTOR

MARKET REPORT

The Australian stock market climbed 1.1 percent on Wednesday March 16, 2022, with the ASX200 up 77.8 points to 7,175.2 points. Fifteen of the Biotech Daily Top 40 stocks were up, 18 fell, six traded unchanged and one was untraded.

Alcidion was the best, up 1.5 cents or 8.6 percent to 19 cents, with one million shares traded. Genetic Signatures, Medical Developments and Starpharma climbed more than five percent; Imugene, Orthocell and Patrys improved four percent or more; Amplia, Mesoblast and Paradigm were up three percent or more; Resmed rose 2.8 percent; Avita, CSL, Pharmaxis and Polynovo climbed more than one percent; with Next Science and Pro Medicus up by less than one percent.

Micro-X led the falls for the second day in a row, down two cents or 10.8 percent to 16.5 cents, with 750,847 shares traded. Resonance retreated 7.4 percent; Nova Eye fell 4.65 percent; Impedimed and Nanosonics were down more than three percent; Clinuvel, Immutep, Oncosil and Universal Biosensors shed two percent or more; Actinogen, Compumedics, Kazia, Opthea, Telix and Volpara were down more than one percent; with Cochlear, Cyclopharm, Emvision and Proteomics down by less than one percent.

HAEMOKINESIS

Haemokinesis says it hopes to raise \$17 million at 20 cents a share to list on the ASX under the code HKX and commercialize its blood group diagnostics.

Haemokinesis said that it would have an indicative market capitalization of \$77.4 million following the initial public offer.

The company said that its blood group diagnostic technology could convert a one-to-fourhour process to a 12-minute-to-one-hour process "eliminating delays and saving resources like O-negative blood".

Haemokinesis chief executive officer Jim Manolios told Biotech Daily: "The diagnostics are essential to match blood types, as the wrong transfusions can sometimes be fatal."

The company said it was established to develop diagnostic platforms in immunehaematology, identifying human blood groups and associated tests, with applications in emergency medicine, and point-of-care diagnostics.

Haemokinesis said it would expand sales of two rapid blood diagnostic platforms and had 24 existing distributors servicing 56 countries with more than 130 diagnostic systems installed across the world.

The company said that it had Conformité Européenne (CE) mark and Australian Therapeutic Goods Administration approvals, and had a US Food and Drug Administration "pathway".

Haemokinesis said its "unique, patented point-of-care diagnostic platform with compelling benefits over current laboratory testing methods and an in-lab platform [was] capable of disrupting the current \$US2.1 billion world market".

The company said that revenue for the 2021 financial year was \$3.9 million.

Haemokinesis said it aimed "to help healthcare professionals provide patients with the best available rapid blood testing technology when every second counts".

The company said that it had a full-suite of blood group analysis products for emergency, routine, donor bank and laboratory testing environments.

Haemokinesis said its rapid blood group tests "fill a gap in clinical requirements, improving patient care and cost efficiencies for customers".

The company said it had "a strong pipeline of new products led by its [group legible immune-haematology format] Glif a bioactive paper that enables an accurate one-minute on-site blood type test".

"This new accurate and rapid test is vital in emergency and urgent care facilities ... [with] laboratory, trauma, in-field and consumer applications," the company said.

Haemokinesis said that Glif was currently sold in the US for pre-donation testing, which did not require FDA approval, with trials continuing at US blood banks, with FDA-directed trials of the laboratory platform to "in the coming months".

The company said its chair was former Monash IVF and Melbourne Pathology chief executive officer and Genera executive chair Lou Panaccio, with directors including former Genetic Technologies and Praemium chief executive officer Michael Ohanessian, Pacific Smiles founder Alex Abrahams and Meda Pharmaceuticals' and The Hydroponics Co (now Epsilon) chief operating officer Debbie Ormsby.

Haemokinesis said its chief executive officer was Jim Manolios, with shareholders including Mr Abrahams and Centennial Coal founder Bob Cameron.

The company said that funds raised would go to working capital, manufacturing instruments and consumables and expanding infrastructure and capacity.

Haemokinesis said the offer would close on March 23, with trading expected to begin on April 8, 2022.

The company said that PAC Partners was the lead manager of the offer and the prospectus was available at: <u>https://www.hkx.automicipo.com.au/</u>.

VICTORIA GOVERNMENT

The Victoria Government says it will provide \$10 million for 20 researchers "to improve survival rates and outcomes for people with cancer".

A media release from Victoria Minister for Health Martin Foley said the projects included the treatment of lung cancer, predicting the spread of breast cancer, developing a cheap genetic test to identify at risk people and a screening tool for cervical cancer.

The media release said projects included \$300,000 for La Trobe University to investigate a new approach to treating the cancer-related wasting syndrome cachexia, which affected 65 percent of all cancer patients and resulted in 35 percent of cancer-related deaths, reducing mobility, quality of life and the effectiveness of treatments.

The State Government said other projects included a diagnostic for general practitioners to identify people most at-risk of undiagnosed cancer and a mobile intervention to increase participation in cervical screening.

The media release said that cancer was a common and major health problem and the five most common cancers were prostate, breast, bowel and lung cancer, and melanoma.

"Victoria is home to world leading cancer treatment, care and research and we are backing those clinicians, scientists and researchers to make ground-breaking discoveries that improve cancer survival rates," Mr Foley said/

"We're supporting work that can change lives, improve outcomes for people with cancer and save families from the heartache of losing a loved one," Mr Foley said.

LBT INNOVATIONS

LBT says its US distributor, Thermo Fisher Scientific's Remel Inc, has "purchase orders for multiple [automated plate assessment system] APAS instruments".

LBT did not disclose the number of APAS instruments ordered, nor their total value. Last year, the company said it sold two APAS Independence instruments and modules to Sonic Healthcare's London subsidiary Health Services Laboratory and LBT chief executive officer Brent Barnes told Biotech Daily that the standard retail price per unit was \$US300,000 (\$A417,000) with a further \$US20,000 (\$A27,780) per year licence fee, but that varied with each deal (BD: May 18, 2021).

Today, the company said that it was the first purchase order by Thermo Fisher through LBT's wholly owned subsidiary Clever Culture Systems.

Late last year, LBT said it would pay the Westphalia, Germany-based Hettich GmbH \$4 million for its 50 percent share of Clever Culture Systems (CCS), taking full ownership of the joint venture (BD: Jan 16, 2022).

Today, the company said the order was "expected to accelerate early sales opportunities and follows the strong customer interest shown in the first six months since the appointment of Thermo Fisher as exclusive distributor for the US".

LBT said the order would support instrument placement among key opinion leaders. The company said the instruments were expected to be shipped progressively over the next four months, with full order shipment expected no later than 31 July 2022.

In the media release to the ASX, Mr Barnes said the purchase was "an indicator of the positive market feedback Thermo Fisher Scientific have received since their appointment as US distributor last year".

"With full ownership of CCS, we are able to work directly with Thermo Fisher to support their sales activities and strategic account placement with key opinion leaders," Mr Barnes said. "This is a clear demonstration of how the simplified ownership structure will help to streamline our commercialization efforts going forward."

LBT was up 1.3 cents or 16.9 percent to nine cents with 2.5 million shares traded.

REDHILL BIOPHARMA

Redhill says Kukbo Co will pay \$US1.5 million (\$A2.1 million), up to \$US5.6 million (\$A7.8 million) for milestones, plus royalties for opaganib for Covid-19 in South Korea. In February, Redhill said two analyses from its 475-patient, phase II/III trial of oral opaganib for severe Covid-19 showed that - despite not meeting its original trial endpoints – the drug demonstrated a 70.2 percent reduction in mortality, with remdesivir and corticosteroids (BD: Sep 15, Oct 5, 2021; Feb 8, 2022).

Today, the company said it would grant Kukbo exclusive rights to commercialization of opaganib in South Korea, as well as right of first offer for opaganib, RHB-107 and Talicia (RHB-105) for Helicobacter pylori, for one or more of South Korea, Japan, Indonesia, Vietnam, Thailand and Malaysia.

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

Today, Redhill chief executive officer Dror Ben-Asher said South Korea was experiencing a spike in Covid-19 cases with the Korea Disease Control and Prevention Agency reporting "almost four million new cases already registered in the first half of March alone". "Together with our partner, Kukbo, we are working hard to bring opaganib to Korean patients in need of new Covid-19 therapeutic options."

On the Nasdaq, Redhill fell two US cents or 1.20 percent to \$US1.65 (\$A2.29) with 678,858 million shares traded.

ENA RESPIRATORY

Ena says it has dosed the first of a 123-person, phase IIa, randomized, double-blind, placebo-controlled challenge trial of INNA-051 as a prophylaxis for influenza. In February, the company said it would partner with the Miami, Florida-based COPD (chronic obstructive pulmonary disease) Foundation to develop its INNA-051 nasal spray for people with chronic lung diseases (BD: Feb 24, 2022).

Today, Ena said it would evaluate the safety, tolerability and antiviral efficacy of INNA-051 against H3N2 influenza virus infection at two intra-nasal spray doses in healthy adults. The company said efficacy would be assessed as the reduction of total viral and total symptoms score in treated versus placebo participants.

Ena said the study would support validation of INNA-051 for pan-antiviral use in those at high-risk of complications from severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2), rhinovirus, respiratory syncytial virus, influenza and other common respiratory viruses.

The company said the trial was being conducted in the UK with results expected by the end of the year.

Ena chief executive officer Dr Christophe Demaison said the study would "take us another step closer to determining whether INNA-051 can provide a fast-acting, easy-to-use therapy to address this unmet need".

Ena said that a phase II Covid-19 post-exposure anti-viral prophylaxis study to determine whether INNA-051 reduces the incidence and severity of symptomatic Covid-19 was expected to begin "shortly".

The company said the study would evaluate whether the nasal spray reduced the magnitude and duration of Sars-Cov-2 nasal shedding, to understand potential broader public health benefits.

Ena is a private company.

ALCIDION

Alcidion says it has a \$1.9 million deal with the Dundee, Scotland-based Tayside National Health Service (NHS) for the provision of its Miya Precision patient monitoring platform. Alcidion said that as part of the five-year agreement, it would provide the Observations and Assessments modules of Miya Precision to Tayside NHS, the third health board in Scotland to adopt its electronic patient monitoring system.

The company said Miya Observations was an early warning system that shared critical information as soon as it was recorded.

Alcidion said the system alerted clinical staff whenever patients showed signs of deterioration, allowing healthcare professionals to focus on those patients immediately in need.

The company said that Tayside NHS employed 14,000 people for a population of more than 400,000 people in the central East of Scotland.

Alcidion managing-director Kate Quirke said "healthcare technology should exist to provide benefits to the people delivering and receiving care".

"It should help to make the right thing to do, the easiest thing to do," Ms Quirke said.

"It is rewarding to see this success story continue to grow in Scotland and to be welcoming another important customer in the UK," Ms Quirke said.

Alcidion was up 1.5 cents or 8.6 percent to 19 cents with one million shares traded.

CRESO PHARMA

Creso says it will send 35,000 Cannaqix 50 marijuana lozenges to its acquisition target, the Lyons, Colorado-based Sierra Sage Herbs LLC as an initial sales run.

In February, Creso said it would buy Sierra Sage for \$US21 million (\$A29.5 million) in shares, with additional milestone payments (BD: Feb 3, 2022).

Today, it said the shipment would come from Creso Pharma Switzerland and would be sold online through Sierra Sage's Good Goo cannabidiol-focused brand.

Creso managing-director William Lay said "our work with the team at Sierra Sage Herbs has continued to progress significantly ahead of the completion of the proposed acquisition".

"Over the last few weeks, we have been working with Jodi [Scott] and her management team to progress initiatives that will allow Creso Pharma to commence a number of value accretive initiatives on closing of the transaction," Mr Lay said.

"The initial shipment of Creso Pharma Switzerland products marks an important milestone and will allow us to test the market, as well as learn how consumers will engage with the company's product suite," Mr Lay said. "This will build an important foundation for us as we progress towards larger product launches upon closing of the transaction."

"We are also very pleased with the completion of an initial Impactive product line through the group's contract manufacturer."

Creso was unchanged at 5.1 cents with 8.1 million shares traded.

ALTHEA GROUP

Regal Funds Management says it has reduced its substantial holding in Althea from 22,946,369 shares (7.48%) to 20,435,513 shares (6.48%).

The Sydney-based Regal said that between September 14, 2021 and March 10, 2022 it bought, sold and was diluted in Althea, with the largest single sale 600,000 shares on December 20, 2021, for \$135,000 or 22.5 cents a share.

Althea was unchanged at 12.5 cents.

IMMURON

Immuron says it has appointed former Polynovo chief executive officer Paul Brennan as an independent non-executive director.

Immuron said Mr Brennan was Polynovo's chief executive officer for seven years from 2015 to 2021.

The company said that previously Mr Brennan was Smith & Nephew Healthcare marketing director for Australia and New Zealand.

Immuron was unchanged at 10.5 cents.