

Biotech Daily

Thursday May 20, 2021

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH UP: IMMUTEP UP 12%; USCOM DOWN 14%
- * ANTEO PLAN: \$32m APPLICATIONS, RAISES \$8m; TOTAL \$20m
- * 4D RECRUITS 1st VQ LUNG IMAGING COHORT
- * PAINCHEK WINS CE MARK, UK MHRA APPROVAL
- * RHINOMED WINS CE MARK FOR RHINOSWAB
- * AZURE TO LIST AS VGI ON NSX
- * MEDLAB MOVE TO SYNTHETIC NANABIS FOR CANCER PAIN TRIAL
- * CRONOS: MARIJUANA SALES UP; ECS TERPENE DISTRIBUTION
- * HEXIMA RENAMES HXP124 'PEZADEFTIDE'
- * RACE APPOINTS PROF MICHAEL KELSO PRINCIPAL SCIENTIST
- * NEUROTECH APPOINTS PROF ALLAN CRIPPS DIRECTOR

MARKET REPORT

The Australian stock market rebounded 1.3 percent on Thursday May 20, 2021, with the ASX200 up 87.9 points to 7,019.6 points. Twenty-one of the Biotech Daily Top 40 stocks were up, 14 fell and five traded unchanged. All three Big Caps were up.

Immutep was the best for the second day in a row, on a preview of trial abstracts, up six cents or 11.9 percent to 56.5 cents, with 9.1 million shares traded. Antisense and Imugene improved more than eight percent; Actinogen rose 6.25 percent; Prescient was up five percent; Alterity and Kazia were up four percent or more; Nanosonics, Opthea and Polynovo were up more than three percent; Clinuvel, LBT, Mesoblast, Oncosil and Paradigm rose more than two percent; Cochlear, CSL, Dimerix, Nova Eye, Pro Medicus, Resmed and Universal Biosensors were up more than one percent; with Neuren and Starpharma up by less than one percent.

Uscom led the falls, down two cents or 14.3 percent to 12 cents, with 1.6 million shares traded. Telix lost 6.6 percent; Proteomics and Resonance retreated more than five percent; Patrys fell 4.35 percent; Pharmaxis was down 3.6 percent; Amplia, Medical Developments, Next Science and Orthocell shed two percent or more; Genetic Signatures was down 1.6 percent; with Avita, Cynata and Volpara down by less than one percent.

ANTEOTECH

Anteo says its \$4 million share plan at 26 cents a share had \$37.1 million in applications and has been increased to \$8 million, taking the total raised to \$20 million.

In April, Anteo said it had raised \$12 million in a placement to institutional and sophisticated investors at the same price (BD: Apr 28, 2021).

Today the company said the funds would be used to accelerate commercialization of its lateral flow tests, build organizational capability, support its battery development program, its life sciences' manufacturing strategy and for the working capital.

Anteotech was up 2.5 cents or 7.9 percent to 34 cents with six million shares traded.

4D MEDICAL

4D Medical says it has completed enrolment of the first cohort of eight participants on its 70-participant trial of ventilation perfusion (VQ) for lung diseases.

4D said the first cohort were scanned at the Coral Gables, Florida-based University of Miami "four months ahead of schedule".

Last year, 4D said its first US research program with the University of Miami Health System would use its XV lung imaging technology to improve assessment and outcomes for patients with chronic lung diseases (BD: Dec 2, 2020).

Today, 4D said the ventilation perfusion combination diagnostic built on the XV lung ventilation analysis software (LVAS) technology to measure both the airflow and blood flow into the lungs without the use of contrast agents, enabling earlier detection and intervention of lung diseases.

The company said the 70-participant trial would include patients with obstructive lung disease, restrictive lung disease and control participants and hoped to scan them over the next six months.

4D said the study objective was to compare its data with nuclear medicine ventricular perfusion scans which took longer and exposed patients to radioactive material.

The company said its ventricular perfusion scans were designed to be completed in less than 10 minutes using standard hospital imaging equipment without any contrast agents.

4D chief executive officer Prof Andreas Fouras said that the ability of the ventricular perfusion product to measure ventilation-perfusion without the use of any contrast agents provided "compelling advantages for clinicians to perform scans more frequently and on a broader patient population".

4D Medical was up 2.5 cents or 1.9 percent to \$1.32.

PAINCHEK

Painchek says its Infant pain assessment software has Conformité Européenne (CE) mark and UK Medicines and Healthcare products Regulatory Agency clearance.

Painchek said the approvals allowed the marketing and sale of Painchek Infant pain assessment in Europe, the UK, Canada, Singapore, New Zealand and Australia.

Painchek chief executive officer Philip Daffas said the company was "delighted to achieve this regulatory milestone ahead of schedule and continue to expand [its] global markets."

"The Painchek Infant application is unique in that it completes a micro-facial analysis through a three-second video assessment and provides the carer with an instant result in relation to the infant's pain severity level," Mr Daffas said.

"Painchek now assesses and automatically documents pain scores for adults who cannot verbalize, adults who can self-report and now infants," Mr Daffas said.

Painchek was up 0.3 cents or 4.6 percent to 6.8 cents with 5.2 million shares traded.

RHINOMED

Rhinomed says it has Conformité Européenne (CE) approval for its nasal swab, Rhinoswab.

In 2020, Rhinomed said the Australian Therapeutic Goods Administration had registered its high load-capturing nasal swab as a class one device for influenza and coronavirus (BD: Nov 25, 2020).

The company previously said the US Food and Drug Administration had registered its nasal swab for the detection of upper respiratory tract infections (BD: Nov 20, 2020). Today, Rhinomed said the CE mark would support the sales of its nasal swab in the European market and followed successful registration with the US Food and Drug Administration and Australian Register of Therapeutic Goods.

Rhinomed fell half a cent or three percent to 16 cents.

AZURE HEALTH TECHNOLOGY (MERGED WITH INVICTUS BIOTECHNOLOGY)

Azure, trading as VGI Health Technology, says it expects to list on the National Stock Exchange (previously Newcastle Stock Exchange) on May 28, 2021 under the code VTL. In April, Azure said its initial public offering for the National Stock Exchange raised \$2,497,000, with the VGI Group investing \$2,250,000 for the companies tocotrienol-based food additives and two phase II-ready clinical development assets (BD: Apr 20, 2021). The company said at that time that "in recognition of the importance of the VGI Group becoming a substantial shareholder" it would change its name to VGI Health Technology, pending shareholder approval.

Azure is a public unlisted company.

MEDLAB CLINICAL

Medlab says its planned 360-patient, phase III trial for cancer bone pain will use a synthetic cannabinoid formulation of its marijuana-based Nanabis.

Last month, Medlab said interim analysis of its 119-patients enrolled observational study showed a 55 percent reduction in pain with Nanabis (BD: Apr 12, 2021).

Today, the company said that based on feedback received from regulators including the US Food and Drug Administration, it believed that a "synthetic pharmaceutical-grade formulation of Nanabis would be preferred over a botanical formulation".

Medlab chief executive officer Dr Sean Hall said the company would refile its investigational new drug application (IND) "to reflect the new formulation which would deliver improved control over costs, certainty of supply, higher levels of purity, manufacturing, and a well-established regulatory pathway".

Dr Hall said the company had produced the first batch of synthetic cannabidiol (CBD) and tetrahydrocannabinol (THC).

"Synthetic CBD now has an FDA-recognized drug master file and Medlab is working to submit a drug master file ... for a 100 percent synthetic THC known as a neat dronabinol," Dr Hall said.

Dr Hall said that a synthetic formulation would allow to more closely control product development variables that could otherwise impact the manufacture and delivery of a pharmaceutical product at scale over a botanical formulation".

Medlab was up 1.5 cents or 8.8 percent to 18.5 cents.

CRONOS AUSTRALIA

Cronos says its marijuana Adaya sales revenue has had an "average quarter-on-quarter increase ... of more than 200 percent" and it will distribute ECS terpenes.

In its most recent Appendix 4C quarterly reports, Cronos said that receipts from customers in the three months to September 30, 2020 was \$111,661, for the three months to December 31, 2020 was \$176,872 and for the three months to March 31, 2021 was \$381,756.

The company said its Adaya range comprised five marijuana oil products, cannabidiol (CBD) dominant Adaya 1:25, CBD-only Adaya CBD 100, the equal CBD and tetrahydrocannabinol THC Adaya 10:10, THC dominant Adaya 20:1 and THC-only Adaya THC 26.

Cronos chief executive officer Rodney Cocks said the "solid quarter-on-quarter growth in sales of our Adaya range of products is validation of our strategy to ensure Australian patients can access Australian manufactured, Australian and [European Union Good manufacturing practice compliant], affordable and available medicinal cannabis products". The company said it has a 12-month market agreement with the Sydney-based ECS Botanics to distribute its CB1 and CB2 terpene blends of Tasmanian cannabis sativa seed oil across Australia.

Cronos was up two cents or 20 percent to 12 cents.

HEXIMA

Hexima says the International Nonproprietary Names program and Classification of Medical Products of the World Health Organization has renamed HXP124 'pezadeftide'. In March, Hexima said it had appointed a scientific advisory board for the development of HXP124 for the toe-nail fungal disease onychomycosis (BD: Mar 9, 2021).

Today, the company said the suffix '-deftide' represented defensin-derived anti-microbial peptides and established pezadeftide as the "first in a new class of anti-fungal molecules". Hexima said it expected pezadeftide to be included in the list of 126 International Nonproprietary Names to be published by World Health Organization's drug information and to be confirmed following a four-month public review and comment period. Hexima was up 2.5 cents or 16.1 percent to 18 cents.

RACE ONCOLOGY

Race says it has appointed Prof Michael Kelso as its principal scientist, effective from July 12, 2021.

Race said Prof Kelso would be responsible for providing scientific leadership, and developing, managing and implementing its pre-clinical and clinical research programs. The company said Prof Kelso had more than 25 years of experience in medicinal chemistry research and development, including oncology, anti-microbial drug development and drug formulation.

Race said Prof Kelso was previously the professor of medicinal chemistry at the University of Wollongong and a National Health and a post-doctoral research fellow at the Jupiter, Florida-based Scripps Research Institute.

The company said Prof Kelso held a Bachelor of Medicinal Chemistry from the University of Wollongong and a Doctor of Philosophy from the University of Queensland. Race was up one cent or 0.3 percent to \$3.21.

NEUROTECH INTERNATIONAL

Neurotech says it has appointed Prof Allan Cripps as a non-executive director, effective from May 19, 2021.

Neurotech said Prof Cripps had experience in the development of immunity in children and mucosal immune mechanisms.

The company said Prof Cripps was currently a professor emeritus at Queensland's Griffith University.

Neurotech said subject to shareholder approval, it would grant Prof Cripps 500,000 options exercisable at nine cents each by May 12, 2023.

Neurotech was up 0.3 cents or 5.3 percent to six cents.