Biotech Daily

Thursday May 21, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: IMPEDIMED UP 36%; PATRYS DOWN 7%**

*** 4D: FDA CLEARS XV LUNG VENTILATION ANALYSIS SOFTWARE**

*** VIVAZOME, CYTIVA DEAL FOR EXOSOME PURIFICATION TECHNOLOGY**

*** TBG: CE MARK FOR SARS-COV-2, COVID-19 TESTS**

*** SIENNA APPOINTS ZOTAL FOR HTERT BLADDER CANCER IN ISRAEL**

*** ALTERITY: 'ATH434 POTENTIAL MSA EFFICACY IN HUMANS'**

*** PRESCIENT REQUESTS 'MATERIAL LICENCE' TRADING HALT**

*** CALEDONIA REDUCES, DILUTED TO 6.6% OF ALCIDION**

*** THC: CANNDEO MARIJUANA AVAILABLE BY SCRIPT IN AUSTRALIA**

MARKET REPORT

The Australian stock market fell 0.41 percent on Thursday May 21, 2020, with the ASX200 down 22.6 points to 5,550.4 points. Eleven of the Biotech Daily Top 40 stocks were up, 19 fell, seven traded unchanged and three were untraded.

Impedimed was the best on no news, up 1.5 cents or 35.7 percent to 5.7 cents, with 15.4 million shares traded. LBT climbed 10.7 percent; Pharmaxis and Starpharma were up more than five percent; Telix was up 4.6 percent; Imugene improved three percent; Pro Medicus rose 2.1 percent; Clinuvel, Cochlear, Cyclopharm and Polynovo were up more than one percent; with Volpara up 0.35 percent.

Patrys led the falls, down 0.1 cents or 7.1 percent to 1.3 cents, with 651,802 shares traded. Paradigm lost 6.3 percent; Medical Developments, Oncosil and Orthocell fell four percent or more; Cynata, Dimerix, Ellex and Opthea were down more than three percent; Avita, Immutep, Kazia, Neuren, Proteomics and Universal Biosensors shed more than two percent; CSL, Next Science and Resmed were down one percent or more; with Genetic Signatures, Mesoblast and Nanosonics down by less than one percent.

4D MEDICAL (FORMERLY 4DX)

Melbourne's 4D says the US Food and Drug Administration has cleared its "four-dimensional" XV lung ventilation analysis software imaging product for sale in the US.
4D said that the XV technology was not intended to replace primary diagnostic tests, such as the molecular tests to prove the presence of Covid-19, but was "designed to provide … quantitative support for diagnosis and follow-up examinations".
4D chief executive officer Dr Andreas Fouras said the XV technology provided "critical information about the functional state of a patient's lungs in the treatment of all illnesses of the lungs, such as asthma, emphysema, pulmonary fibrosis and lung cancer".
"In the case of Covid-19, XV can be used to triage patients into the right treatment setting and to quickly determine how well a treatment is working," Dr Fouras said.
4D said the XV could be implemented immediately, using existing hospital and clinical infrastructure with no capital expenditure or training required.
The company said that the XV was provided as a software-as-a-service diagnostic tool, available through an internet "cloud" subscription.
4D said that imaging departments conduct an X-ray sequence using existing fluoroscopy equipment and the software "rapidly and automatically analyzes and applies its proprietary algorithms to identify and quantify any functional impairment".
The company said that the XV lung ventilation analysis software generated a Ventilation Report which was sent to the hospital to enable clinicians to determine the most effective treatment course of action and allocation of finite hospital resources.
4D said the end-to-end process could be completed and generate a report in three hours.
"The clinical trials and peer reviews that have been undertaken over the past 15 years in conjunction with the FDA's 510(k) clearance, provide a solid foundation for 4D Medical to obtain regulatory approval to offer its XV technology in other geographic markets such as Australia, Europe and Asia," Dr Fouras said.
4D said it began the Australian Therapeutic Goods Administration approval process in January 2020 and had partnerships with medical researchers and hospitals in Australia for clinical trials of the XV technology.
Dr Fouras told Biotech Daily that 4D had "a small US sales team and we are increasing it as we speak".
"We want to build the evidence and data and then make a decision on partnering for distribution," Dr Fouras said. "It is quite likely we will keep it in-house."
Last year, the then 4Dx said it had raised $15 million in a pre-initial public offer and intended to conduct an initial public offer within 12 months (BD: Dec 10, 2019).
4D is a public unlisted company.

VIVAZOME THERAPEUTICS

Vivazome says it will collaborate with Cytiva to develop "a high-efficiency downstream separation and concentration process for exosome production".
Vivazome said it would supply the Uppsala, Sweden-based Cytiva with "substantial quantities of exosome-rich, cell culture supernatant" produced by its preferred cell type".
The company said Cytiva would evaluate its chromatography resins and fibre materials for their potential to separate and concentrate exosomes, focusing on high purity, fast flow rates and scalability.
Vivazome chief executive officer Dr David Haylock said the two companies "recognize that development of a high-efficiency downstream separation and concentration process is key to manufacture of therapeutic exosomes and realizing their therapeutic potential".
Vivazome is a private company.

TBG DIAGNOSTICS

TBG says it has Conformité Européenne (CE) mark approval for severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) and Covid-19 tests.

TBG said that Taiwan subsidiary TBG Biotechnology Corp developed the Exprobe Sars-Cov-2 RNA-based kit using polymerase chain reaction (PCR) technology with multiplex design to detect distinctive segments of genes of the Sars-Cov-2 virus in a single reaction, commonly used to confirm active infection by the virus.

The company said the Sars-Cov-2 immunoglobulin G and M (IgG and IgM) rapid test used a droplet of blood, serum or plasma and was a lateral flow assay able to detect IgG and IgM antibodies against specific protein epitopes of Sars-Cov-2.

TBG said it expected the antibodies test to take 15 minutes to complete and detect the presence of specific antibodies in the blood, serum and plasma, which were usually generated seven to 10 days after infection and could last for weeks.

The company said the antibodies test was used to confirm if a person had been infected with the virus.

TBG said that CE mark indicated that the tests met “essential health, safety, and environmental protection requirements of the applicable European regulations to allow the sale of the kit throughout the European Economic Area as well as any country that accepts CE-mark, subject to satisfying regulatory requirements and obtaining import permits for individual countries”.

The company said that both tests were manufactured by TBG Biotechnology Corp. in Taiwan and would be exported from Taiwan subject to meeting the regulatory requirements of the destination country.

“Together, these two test products are expected to be able to confirm symptomatic individuals with an active Sars-Cov-2 viral infection and those who have been infected by Sats-Cov-2 and generated a specific antibody response,” TBG said.

TBG chairman Jitto Arulampalam told Biotech Daily that the antibodies test was the same as the TBG Biotechnology Xiamen Inc nucleic acid diagnostics kit for Covid-19, which had been held back awaiting approval from the People’s Republic of China.

In March, TBG requested a pause in trading followed by a trading halt “pending an announcement in relation to certification of a TBG Biotechnology Xiamen Inc novel coronavirus diagnostic kit”, by which time the company’s share price had climbed as much as 27.4 cents or 1053.8 percent to 30 cents before retreating to 27 cents before the trading halt (BD: Mar 17, 2020).

On March 18, the company said that 46.65 percent subsidiary TBG Xiamen had CE mark approval for its Covid-19 nucleic acid diagnostics kit (BD: Mar 18, 2020).

The next day, TBG was suspended by the ASX “pending further inquiries” following an ASX “aware” query, in which the company said it became aware of CE mark certification on Saturday March 14, but “had only received informal notification … and therefore did not consider that they had all information and materials necessarily required in order to confirm this matter and release an announcement to the market” (BD: Mar 19, 2020).

In April, TBG told the ASX that it “genuinely and reasonably believed” that the test’s CE mark approval was confidential even though its share price had climbed 1053.8 percent (BD: Apr 15, 2020).

On April 6, TBG said that China had banned the export of its Covid-19 diagnostics kits without the required China medical device product registration.

Mr Arulampalam told Biotech Daily that TBG Xiamen would apply for Chinese approval and was also considering manufacturing the kits outside China (BD: Apr 6, 2020).

TBG remained suspended at 27 cents.

SIENNA CANCER DIAGNOSTICS

Sienna says Tel Aviv's Zotal has been appointed as the distributor of its human telomerase reverse transcriptase (hTERT) in-vitro diagnostic for bladder cancer in Israel.
Sienna said Zotal would sell the hTERT test to pathology laboratories to assist in the diagnosis of bladder cancer and would source several reference laboratories to adopt the test, while it would provide sales, marketing and technical training to Zotal.
The company said that it would work with Zotal on product registration and reimbursement applications to the Israel Ministry of Health's Department of Medical Devices, which it expected to take six months.
Sienna said Israel had a population of about nine million people, had a growing elderly population and had a medical device market worth about $US2.4 billion ($A3.66 billion).
Sienna was up 0.3 cents or 5.2 percent to 6.1 cents.

ALTERITY THERAPEUTICS (FORMERLY PRANA BIOTECHNOLOGY)

Alterity says the phase I trial of ATH434 (previously PBT434) for multiple system atrophy shows it crosses the blood brain barrier in humans at levels indicating efficacy.
Alterity said the trial evaluated the safety, tolerability and pharmacokinetics of ATH434 and found that clinically tested doses achieved concentrations in the brain comparable to or exceeding those associated with efficacy in animal models (BD: May 6, Jul 29, 2019).
The company said safety data indicated that ATH434 was well tolerated and demonstrated a similar adverse event profile for adults and older adults over 65 years.
Alterity said the data supported plans to clinically test ATH434 for multiple system atrophy, a form of atypical Parkinsonism.
Alterity chief medical officer Dr David Stamler said that "because we're treating the underlying cause of disease by targeting alpha synuclein, I think we have potential to affect all aspects of disease - the motor symptoms, the blood pressure problems, gait and balance, and even bowel and bladder dysfunction".
The company said the presentation was from an abstract, titled 'A Phase I study of PBT434, a Novel Small Molecule Inhibitor of a-Synuclein Aggregation, in Adult and Older Adult Volunteers', published in the journal Neurology and was available at: https://n.neurology.org/content/94/15_Supplement/4871.
Alterity was unchanged at two cents.

PRESCIENT THERAPEUTICS

Prescient has requested a trading halt "pending an announcement by the company to the market regarding a material licence agreement".
Trading will resume on May 25, 2020 or on an earlier announcement.
Prescient last traded at 4.5 cents.

ALCIDION GROUP

Caledonia Nominees says it has reduced and been diluted in Alcidion from 71,702,358 shares (7.96%) to 65,802,358 shares (6.64%).
The Sydney-based Caledonia said it was further diluted by 0.72 percent on November 11, 2019 in a $16.2 million placement at 18 cents a share (BD: Nov 5, 2019).
The company said that between April 30 and May 18, 2020 it sold 5,900,000 shares for $934,047.48 or 15.8 cents a share in an on-market trade.
Alcidion was unchanged at 15.5 cents with 1.4 million shares traded.

THC (THE HYDROPONICS CO) GLOBAL GROUP

THC says that its first Australian-produced full spectrum marijuana product Canndeo is available by prescription in Australia.

THC said the marijuana product would be available through the Australian special access scheme and it would continue the progressive roll-out its Australian-produced medicines over the coming months.

THC was up 5.5 cents or 16.7 percent to 38.5 cents with 2.5 million shares traded.