

Biotech Daily

Thursday March 19, 2020

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: GENETIC SIGNATURES UP 10.5%; OPTHEA DOWN 24%
- * LUINA BIO, GRIFFITH UNI 'COLLABORATE ON COVID-19 VACCINE'
- * ATOMO: 'TO DEVELOP COVID-19 RAPID SELF-TESTS'
- * VICTORIA REOPENS 2 HOSPITALS FOR COVID-19
- * PAINCHEK: 25k BED LICENCES TRIGGERS \$1.25m MILESTONE
- * LBT STUDY TO VALIDATE APAS INDEPENDENCE VRE MODULE
- * BIOTRON RECEIVES \$753k R&D TAX INCENTIVE
- * ASX SUSPENDS TBG; RESPONDS TO ASX CE MARK AWARE QUERY
- * MEDIBIO COMPLETES SLEEP STAGE ALGORITHM TEST
- * CANN GLOBAL: OBSIDIAN REFINANCES L1 NOTES
- * IMPRESSION: MARIJUANA INHALERS FOR LUNG DISEASE
- * SOMNOMED TAKES CAPITAL RAISING HALT TO SUSPENSION
- * RESPIRI TAKES CAPITAL RAISING HALT TO SUSPENSION
- * MGC REQUESTS SWISS COVID-19 MARIJUANA J-V TRADING HALT
- * REGAL FUNDS TAKES 13% OF OPTHEA
- * CLARITY APPOINTS PROF OLIVER SARTOR ADVISOR

MARKET REPORT

The Australian stock market fell 3.44 percent on Thursday March 19, 2020, with the ASX200 down 170.3 points to 4,782.9 points. Six of the Biotech Daily Top 40 stocks were up, 28 fell, five traded unchanged and one was untraded.

Genetic Signatures was the best, up 10.5 cents or 10.5 percent to \$1.105, with 316,272 shares traded. Proteomics was up 9.5 percent; Resonance rose five percent; CSL was up 4.6 percent; Clinuvel climbed 2.3 percent; with Cochlear, Ellex and Neuren up by less than one percent.

Opthea led the falls, down 39.5 cents or 24.0 percent to \$1.25 with 1.8 million shares traded. Impedimed and LBT lost more than 21 percent; Orthocell fell 16.7 percent; Volpara shed 13.2 percent; both Oncosil and Uscom were down 12.5 percent; Amplia, Antisense, Medical Developments and Telix were down 10 percent or more; Cynata and Paradigm retreated more than eight percent; Patrys lost 7.1 percent; Dimerix, Kazia, Pharmaxis and Pro Medicus shed six percent or more; Actinogen, Imugene, Nanosonics and Next Science were down five percent or more; Mesoblast and Starpharma fell more than four percent; Immutep, Prescient and Universal Biosensors were down more than three percent; Polynovo shed two percent; with Resmed down 0.7 percent.

LUINA BIO, GRIFFITH UNIVERSITY

Luina Bio says it has a memorandum of understanding with Brisbane's Griffith University for the development of a coronavirus vaccine.

Luina said it had a "wealth of contract manufacture capabilities and experience" and Griffith University's Centre for Cell Factories and Biopolymers, at the Griffith Institute for Drug Discovery had developed "a rapid response vaccine platform technology" that enabled the design and manufacture of a particulate viral vaccine.

The company said that the vaccine platform technology allowed for low cost, and largescale manufacturing of new pilot vaccine candidates ready for pre-clinical and clinical testing against an emerging viral threat.

Luina said that generation of such candidates could occur in a very short time frame, typically two to three months from commencement of the vaccine design process.

"These features make this technology ideally suited for vaccine development against emerging threats such as the coronavirus," the company said.

Luina chief executive officer Les Tillack told Biotech Daily that with optimal conditions the vaccine candidate could be ready for human clinical trials in six to 12 months.

Mr Tillack said that the importance of the Griffith University-Luina process was that it could produce the vaccine "quickly and at a fraction of the cost of normal vaccines".

Kuina said the agreement meant it would work with Griffith University on a variety of vaccine manufacturing projects over the next five years.

Mr Tillack said that the use of Escherichia coli fermentation kept costs down, could be readily scaled and was a proven technology.

The company said Griffith University had funded Covid-19 vaccine candidate proof-of-principle studies and further funding was being sought through new government initiatives. Luina is a private company.

ATOMO DIAGNOSTICS

Atomo says it is working with device and diagnostics manufacturing customers to develop new rapid blood self-tests for Covid-19.

Earlier this month, Atomo said it hoped to raise up to \$30 million at 20 cents a share to list on the ASX and commercialize its HIV tests (BD: Mar 5, 2020).

Today, the company said the Covid-19 blood tests would use its Atomo device to collect and deliver a controlled volume of blood to test for the infection by detecting the presence of antibodies generated in response to the virus.

Atomo said the tests were intended for use by individuals to self-test and could be used by health professionals to screen patients.

The company said the Covid-19 blood tests would be integrated into its existing rapid test platform, which was currently used for HIV screening and differentiating between viral and bacterial upper respiratory infections.

In its supplementary prospectus, the company said global diagnostic companies were seeking access to its rapid test devices as a platform for their own Covid-19 tests. Atomo said one test had China National Medical Products Administration approval as a professional rapid diagnostic test and another was being evaluated in France and Spain. Atomo chief executive officer John Kelly said the "in the past few weeks we have received urgent inbound enquiries from several diagnostic companies based in Europe, the US and China that have recently developed blood-based rapid antibody tests for Covid-19". Mr Kelly said emergency use regulatory approvals processes have been implemented by a number of regulators to fast-track approvals to reduce time to market for Covid-19 tests. Atomo is a public unlisted company.

VICTORIA GOVERNMENT.

Victoria says that it will spend more than \$80 million to provide 84 beds at the old Peter MacCallum Cancer Hospital and 45 beds at Geelong's Baxter House.

A media release from Premier Daniel Andrews and Minister for Health Jenny Mikakos said that the Government would spend an extra \$437 million to respond to the Covid-19 pandemic, "on top of the \$100 million elective surgery blitz announced on Sunday". The State Government said that the funds would include "new beds, additional equipment,

The State Government said that the funds would include "new beds, additional equipment funding for [emergency departments] and [intensive care units], additional resourcing for pandemic containment activities and support for workforce continuity throughout the pandemic".

The media release said that a further 140 beds would be funded at Casey Hospital.

PAINCHEK

Painchek says it has more than 44,000 approved bed licenses and a 25,000-bed milestone triggers a \$1.25 million payment from the Federal Government. Painchek said it had a \$5 million grant agreement with the Federal Government for the use of Painchek for residents living with dementia or cognitive impairment. The company said that it had a total of 44,000 approved bed licences for its paid recognition software system and it planned to reach 100,000 Federal Government funded dementia bed licences this year.

Painchek was unchanged at 6.8 cents with 6.4 million shares traded.

LBT INNOVATIONS

LBT says a study will validate its APAS Independence vancomycin-resistant Enterococcus module for commercial use in Australia and the European Union.

LBT said the study would compare the performance of the automated plate assessment system (APAS) device with the vancomycin-resistant Enterococcus (VRE) module against the interpretation of three blinded microbiologists, and would be completed using internal resources, not impacting current cash flow forecasts.

The company said the study would provide evidence of clinical performance and formal validation required for regulatory clearance and release to the market.

LBT said the module would expand the number of tests customers could run on the APAS device and would provide a second module for surveillance of critical organisms related to infection control.

The company said the VRE analysis module would be sold as an additional annual licence fee to the urine and methicillin-resistant Staphylococcus aureus (MRSA) modules already available.

LBT chief executive officer Brent Barnes said, "commencing the VRE analysis module clinical study is another step forward for the APAS technology by increasing the number of tests our customers can process using the APAS instrument".

"Once complete, this will enable us to meet more of the needs of our customers and support future sales of the APAS Independence," Mr Barnes said.

"The work required to develop the VRE analysis module has been completed through our multi-disciplinary APAS development team bring together expertise in microbiology, software development and artificial intelligence," Mr Barnes said.

LBT fell 2.5 cents or 21.7 percent to nine cents with 1.6 million shares traded.

BIOTRON

Biotron says it has received \$753,026 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Biotron said the rebated related to expenditure for the year to June 30, 2019. Biotron fell 1.1 cents or 12.4 percent to 7.8 cents with 8.5 million shares traded.

TBG DIAGNOSTICS

The ASX has suspended TBG from official quotation "pending further inquiries" and following an ASX "aware" query.

Yesterday, TBG said its 46.65 percent subsidiary TBG Biotechnology Xiamen Inc had Conformité Européenne (CE) mark approval for its Covid-19 nucleic acid diagnostics kit and told the ASX it was not aware of any information it had not announced which, if known, could explain recent trading in its securities (BD: Mar 18, 2020).

The ASX said the company's share price rose 1,053.8 percent from 2.6 cents to 30 cents "in the last few days" and noted a significant increase in the trading volume.

According to Commsec data, TBG last traded at 2.6 cents on February 26 with no trades until Monday March 16 when it opened at 10 cents and closed at 14 cents, opening at 14.5 cents on March 17 and closing at 27 cents for a trading halt for the news (BD: Mar 17, 18, 2020).

Today, TBG responded to an ASX aware query saying it became aware of CE Mark certification on Saturday March 14, 2020 when director Dr Stanley Chang was informally notified by operations personnel in China.

The company said that Dr Chang notified TBG's Australian-based directors Jitto Arulampalam and Emily Lee by telephone on March 14, 2020, but they "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."

TBG said Dr Chang received formal confirmation on the evening of Monday March 16, and the company received documentation on Tuesday March 17 at 12.45am.

The company said its directors "understood and reasonably believed that the relevant information remained confidential" between March 14 and March 17, 2020.

On March 16, the share price opened at 10 cents from 2.6 cents and closed at 14 cents. On March 17, it opened at 14.5 cents and climbed as high as 30 cents prior to the trading halt at 27 cents.

TBG was in a suspension and last traded at 27 cents.

MEDIBIO

Medibio says it has completed its sleep stage algorithm test Stager, which is part of its depressive burden development platform MEB-001.

Medbio said Stager used an electroencephalogram (EEG) and an electrocardiogram (ECG) to score sleep study results during sleep stages and it believed Stager had "commercial value in itself".

The company said it expected to file a 510(k) submission to the US Food and Drug Administration in June 2020, following completion of a validation phase to test up to 70 patients.

Medibio was unchanged at 0.5 cents with 2.8 million shares traded.

CANN GLOBAL

Cann Global says Obsidian Global GP will acquire all 2,600,000 convertible notes held by L1 Capital Global Opportunities Master Fund through a refinancing agreement.

In November, Cann Global said it would issue the Melbourne, New York and Grand Cayman Islands-based L1 Capital 2,600,000 convertible notes to raise \$2.22 million after costs (BD: Nov 5, 2019).

Today, the company said the maturity date of the convertible notes would be extended to 80 days from the execution date to allow shareholder approval of replacement notes with a March 31, 2021 maturity date.

Cann Global said it would issue Obsidian 375,556 additional notes and 25,000,000 shares in consideration for the refinancing, which would be held as collateral shares.

The company said that on receiving the funds from Obsidian, L1 would reinvest a further \$862,000 through a \$250,000 placement at 1.0 cent a share, with a free attaching option at 2.5 cents a share for three years, and \$612,000 for 680,000 convertible notes issued by Cann Global and its subsidiary Medical Cannabis Research Group (MCRG).

The company said the new L1 notes would be issued at 90 cents per note and could be converted into either Cann Global or MCRG shares, with the funds to be used for commercialization of its multiple sclerosis research, by MCRG and the Haifa, Israel-based Technion and for general working capital.

Cann Global was unchanged at 0.8 cents with 3.2 million shares traded.

IMPRESSION HEALTHCARE

Impression says it has placed an initial order for 500 marijuana inhalers for lung disease from pharmaceutical manufacturer Entourage Therapeutics.

Impression said the Fall River, Massachusetts-based Entourage granted it exclusivity over the pressurized, metered dose product in Australia, which would be distributed in Australia under the special access scheme.

The company said it expected to generate \$125,000 in revenue from the order. Impression was up 0.2 cents or 5.4 percent to 3.9 cents with 4.65 million shares traded.

SOMNOMED

Somnomed has requested a voluntary suspension "pending an announcement regarding a capital raising".

On Tuesday, Somnomed requested a trading halt "pending an update of trading conditions as a result of Covid-19" (BD: Mar 17, 2020).

Today, the company said it expected to make the announcement on March 24, 2020. Somnomed last traded at \$2.00.

RESPIRI

Respiri has requested a voluntary suspension to follow the trading halt requested earlier this week "pending an announcement in relation to a proposal capital raising initiative" (BD: Mar 17, 2020).

Respiri last traded at 7.4 cents.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC has 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. Trading will resume on March 23, 2020 or on an earlier announcement. MGC last traded at 1.7 cents.

OPTHEA

Regal Funds Management says it has increased its substantial shareholding in Opthea from 31,391,439 shares (11.66%) to 34,346,537 shares (12.76%).

The Sydney-based Regal Funds said that it bought and sold shares between December 10, 2019 and March 11, 2020, with the single largest purchase 5,214,817 shares on March 11 for \$13,975,710 or \$2.68 a share.

Opthea fell 39.5 cents or 24.0 percent to \$1.25 with 1.8 million shares traded.

CLARITY PHARMACEUTICALS

Clarity says it has appointed medical oncologist and prostate cancer specialist Prof Oliver Sartor to its advisory board.

Clarity said Prof Sartor was a professor of cancer research and medical director of the Tulane Cancer Centre and the assistant dean of oncology at the New Orleans, Louisiana-based Tulane University School of Medicine.

The company said Prof Sartor was the medical oncology chair of the genito-urinary committee of NRG Oncology and was previously on the National Cancer Institute's board of scientific counsellors (clinical sciences and epidemiology) and was chairman of the US Department of Defence's prostate cancer integration panel.

Clarity said that Prof Sartor had chaired five data monitoring committees for phase III trials that lead to US Food and Drug Administration approval, had published more than 400 peer-reviewed articles and had more than 25,000 citations.

The company said that Prof Sartor had been the principal or co-principal investigator "on multiple national and international advanced prostate cancer trials" including pivotal trials for FDA approvals.

Clarity said Prof Sartor held a Doctor of Medicine from Tulane University. Clarity is a public unlisted company.