Biotech Daily

Monday March 30, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: GENETIC SIGNATURES UP 24%; PATRYS DOWN 14%**

*** GENETIC SIGNATURES SARS-COV-2 TEST 'IN USE, PENDING APPROVAL'**

*** CELLMID SELLS CHINA COVID-19 ANTIBODY TEST; SALES GUIDANCE**

*** CYCLOPHARM FILES FDA NDA FOR TECHNEGAS**

*** LBT FILES FDA 510(k) FOR APAS INDEPENDENCE MRSA MODULE**

*** MESOBLAST: 70-PATIENT SUB STUDY: REVASCOR BEATS SALINE**

*** OPTHEA COMPLETES OPT-302 COMBO TRIAL FOR DME**

*** RESAPP, COVIU INTEGRATE TELE-HEALTH RESPIRATORY DIAGNOSTIC**

*** SUDA: 'ARTIMIST ON HOLD INDEFINITELY'**

*** BENITEC: COURT APPROVES US MOVE, FIRB TRADING HALT**

*** PRO MEDICUS BUYS-BACK 34k SHARES, RENEWS 10% BUY-BACK**

*** BOD, SWISSE LAUNCH 9 HEMP SEED OIL PRODUCTS**

*** LIFESPOT PLEADS SCHULTZ, FEVER TALKS TO ASX 306% QUERY**

*** IMPEDIMED REQUESTS CAPITAL RAISING TRADING HALT**

*** PYC REQUESTS 'MATERIAL RESULTS' TRADING HALT**

*** MICRO-X APPOINTS DAVID KNOX DIRECTOR**

*** GI DYNAMICS LOSES DIRECTOR TIMOTHY BARBERICH**

*** RESAPP LOSES DIRECTOR NATHAN BUZZA**

*** ESENSE LOSES 5-MONTH DIRECTOR MICHAEL EDWARDS**

MARKET REPORT

The Australian stock market climbed 7.0 percent on Monday March 30, with the ASX200 up 339.0 points to 5,181.4 points.

Twenty-two of the Biotech Daily Top 40 stocks were up, 12 fell, three traded unchanged and three were untraded. All three Big Caps were up.

Genetic Signatures was the best, up 26 cents or 23.6 percent to $1.36, with 1.3 million shares traded. Cyclopharm climbed 16.3 percent; Actinogen was up 15.8 percent; CSL and Pharmaxis were up more than 12 percent; Avita was up 10.75 percent; Cochlear, Immutep and Polynovo improved more than nine percent; Mesoblast, Pro Medicus, Resmed and Uscom rose more than six percent; Compumedics and Nanosonics improved five percent or more; Cynata, Medical Developments, Oncosil, Orthocell and Proteomics were up four percent or more; Telix, Neuren and Next Science were up three percent or more; Starpharma was up 1.3 percent; with Clinuvel up 0.95 percent.

Patrys led the falls, down 0.2 cents or 14.3 percent to 1.2 cents with 800,000 shares traded. Alterity lost 12.5 percent; Antisense fell 9.6 percent; Universal Biosensors shed 6.7 percent; Imugene and Kazia were down more than five percent; LBT and Opthea fell more than four percent; Ellex lost 3.6 percent; Resonance retreated two percent; Volpara shed 1.5 percent; with Paradigm down by 0.95 percent.

GENETIC SIGNATURES

Genetic Signatures says it has applied for regulatory approval of its Sars-Cov-2 Virus diagnostic, which is being supplied in Europe and Australia under exemptions.
Last month, Genetic Signatures said it had supplemented its Easyscreen respiratory pathogen test to identify the presence of the severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) and had expedited a validation program, collaborating with local and international parties, to obtain the data required for international approvals as rapidly as possible (BD: Feb 26, 2020).
Today, the company said it had applied for Conformité Européenne mark approval and Australian Therapeutic Good Association registration and planned to apply for the US Food and Drug Administration emergency use authorization.
Genetic Signatures said the regulatory bodies had to approve the real-time polymerase chain reaction (PCR) assay that identified Sars-Cov-2.
The company said that licenced Australian laboratories were permitted to self-validate the tests and use the kits commercially and it had begun suppling these laboratories.
Genetic Signatures said the CE mark approval would allow continued supply in Europe and the UK, as the regulatory exemptions used for current supply were for a defined period.
Genetic Signatures chief executive officer Dr John Melki said that “customers will be able to use the test to screen for Sars-Cov-2 on its own or as part of our existing Easyscreen respiratory pathogen detection kit”.
The company said that the test could be used with equipment currently supplied by Genetic Signatures “allowing for rapid detection of up to 188 patient samples in 4.5 hours with minimal hands-on time for laboratory technicians”.
Genetic Signatures climbed 26 cents or 23.6 percent to $1.36 with 1.3 million shares traded.

CELLMID

Cellmid says it has a supply agreement to distribute Guangzhou Wondfo Biotech's rapid antibody diagnostic test for Covid-19, the disease caused by Sars-Cov-2 (see above).
Cellmid said that through the Guangzhou, Guangdong-based Wondfo Biotech's authorized distributor Australian Application Pty Ltd it would "pay a fixed price for each test" and had placed its first order but did not specify the number of tests ordered and said it did not have any purchase agreements or orders from Australian customers yet.
The company said the Covid-19 rapid diagnostic was produced in an Australian Therapeutic Goods Administration-approved facility in China and available immediately.
Cellmid said the test was in a small disposable kit that took 10 microlitres of patient serum or 20 microlitres of whole blood and used a lateral flow colloidal gold-based detection method against viral specific immunoglobulin G and M, delivering results in 15 minutes.
The company said validation studies of 596 samples showed specificity of 99.57 percent, a day-3 of infection sensitivity of 86.43 percent, and day-5 sensitivity of 95.0 percent, and the test kits were "stable at room temperature, 2°C to 30˚C, for up to one year".
Cellmid said the test had been approved as a point-of-care test by the Australian Therapeutic Goods Administration on March 25, 2020, by China's NMPA on February 24, 2020 and received Conformité Européene (CE) mark on March 5, 2020 with the UK, Belgium, Spain and Germany already using the product.
Cellmid chief executive officer Maria Halasz said that "widespread Covid-19 testing, isolation of those testing positive and early treatment are the best methods to control the spread if infection, while saving lives and medical resources".
Separately, Cellmid said that while it had "not seen significant impact to its [hair growth] sales and businesses at this stage, there are several uncertainties that mean it would be unlikely that the company's operations would remain the same".
The company said it would withdraw its previous guidance that it would achieve operational profitability for its consumer business by July 2020, and said it would separate Lyramid into a wholly independent entity backed by independent funding and/or a partnership with a biopharmaceutical company by the end of 2020.
Cellmid climbed 21.1 cents or 213.1 percent to 31 cents with 24.0 million shares traded.

CYCLOPHARM

Cyclopharm says it has lodged a US Food and Drug Administration new drug application for its Technegas nuclear medicine lung ventilation imaging agent.
Last week, Cyclopharm said it had reports of increased use of Technegas to differentiate between Covid-19 and pulmonary embolism where laboratory tests results were not fast enough (BD: Mar 24, 2020).
Today, the company said it had submitted a priority review application and if successful, the review date would be reduced from 10 months to six months following the initial 60-day submission review period.
Cyclopharm said it has additionally submitted a fee waiver request and was "confident … that [it would] qualify for either a significant fee reduction or a complete waiver to the $US2.9 million application fee".
Cyclopharm managing-director James McBrayer said that the application was "a tremendous milestone and achievement for the company".
"We are confident of securing [FDA] approval within the next 12 months," Mr McBrayer said.
Cyclopharm was up 14 cents or 16.3 percent to $1.00.

LBT INNOVATIONS

LBT says it has filed for US Food and Drug Administration 510(k) approval of its APAS Independence methicillin-resistant Staphylococcus aureus (MRSA) analysis module.
Last year, LBT said it had FDA approval for its automated plate assessment system (APAS) Independence and associated urine analysis module, and would use the approval as a predicate device for the MRSA, or “golden staph”, module (BD: May 20, 2019).
In September, the company said that it had Conformité Européenne (CE) mark approval for APAS Independence with the MRSA module (BD: Sep 16, 25, 2019).
Today, LBT said the submission was an “important regulatory milestone” and it had a 90-day review period following submission during which it could communicate with the FDA.
The company said the timeline might be impacted by the Covid-19 pandemic.
LBT said that if the submission was successful, it would have two analysis modules for sale in the US which could address 50 to 70 percent of cultured specimens processed by US laboratories.
LBT fell half a cent or 4.8 percent to 10 cent with 1.1 million shares traded.

MESOBLAST

Mesoblast says data from a 70-patient sub-study from a trial of its mesenchymal precursor cells for heart failure shows the stem cells to be superior to saline.
In 2018, Mesoblast said a 159-patient, investigator-initiated phase II trial of mesenchymal precursor cells for heart failure at New York’s Mt Sinai Hospital did not meet its primary endpoint, but showed benefit for gastrointestinal bleeding, and said that the results “could meet requirements for an approvable [US Food and Drug Administration] regulatory endpoint (BD: Nov 12, 2018).
Today, the company said the sub-study results, presented at an American College of Cardiology virtual meeting, showed that mesenchymal precursor cells compared to controls had a “beneficial effect on [left ventricular assist device] weaning, major mucosal bleeding, serious adverse effects and readmissions in ischemic heart failure patients”.
The company said the Revascor group had a mean proportion of temporary weans from LVAD support of 64 percent compared to the control group’s 43 percent.
Mesoblast said the Revascor group’s rate of mucosal bleeding 4.2 percent compared to the control group’s rate of 28 percent.
The company said that the Revascor group had fewer serious adverse effects and fewer readmissions.
Mesoblast said its 566-patient phase III trial of Revascor for advanced chronic heart failure planned to read results in mid-2020.
Mesoblast was up nine cents or 6.9 percent to $1.39 with 4.2 million shares traded.

OPTHEA

Opthea said it has completed dosing and week-12 visits of 144 patients in a phase IIa trial of OPT-302 with aflibercept, marketed as Eylea, for diabetic macular oedema.
Opthea managing-director and chief executive officer Dr Megan Baldwin said the company was “grateful to have reached this clinical milestone, particularly given the current challenges presented by the Covid-19 pandemic”.
The company said its clinical activities including its phase III trial of OPT-302 for wet age-related macular degeneration were “on-going and not currently impacted by the Covid-19 situation”.
Opthea fell 7.5 cents or 4.1 percent to $1.73 with 651,232 shares traded.

RESAPP HEALTH

Resapp says that with Sydney's Coviu has completed an initial integration of Resappdx-EU into Coviu's telehealth platform.

Last year, Resapp said the integration would access the more than 5,500 clinicians who used the Coviu platform, which allowed healthcare providers to offer services directly to patients through video consultation (BD: Nov 28, 2019).

Today, the company said it had a binding commercial term sheet with Coviu and had agreed to a test fee of $5 to $10 for the use of Resappdx-EU on Coviu's telehealth platform.

Resapp said the non-exclusive licence would have an initial term of two years and could be extended by mutual agreement, the companies intended to progress to a formal licence and have Resappdx-EU available for use by all clinicians on Coviu's platform within a few months.

Resapp was up 6.5 cents or 46.4 percent to 20.5 cents with 41.0 million shares traded.

SUDA PHARMACEUTICALS

Suda says it has placed its Artimist paediatric malaria oral spray program on hold indefinitely due to failed regulatory approval attempts.

Last year, Suda said the Australian Therapeutic Goods Administration denied marketing approval for Artimist and refused to reconsider, saying Artimist had been denied due to "an overall negative benefit-to-risk profile" and it could be misused or abused (BD: Jul 18, Oct 1, 4, 2019).

Today, the company said it had decided that it would "no longer commit resources to the project and all steps in seeking to obtain regulatory approval will come to an end".

Suda said that it did not believe the decision to halt the Artimist program would impact the operations of the company moving forward.

Suda fell 0.3 cents or 6.7 percent to 4.2 cents.

BENITEC

Benitec says the Supreme Court of Queensland has given approval for the US-based Benitec Biopharma to be Benitec's parent company, triggering a trading halt.

Last year, Benitec said that if the scheme was approved, shareholders would receive one share in Benitec Biopharma or Holdco for every 300 Benitec shares held at the April 6, 2020 record date (BD: Nov 27, 2019).

In February, the company said that if the Supreme Court approved the scheme, Benitec would be suspended from trading on the ASX, a share sale facility would be held on April 6 and shares would be implemented to shareholders and trading would commence on the Nasdaq (BD: Feb 7, 2020).

Today, Benitec said that the implementation date was April 15 and it would begin to issue Holdco shares to shareholders on April 22, 2020.

In a separate announcement, the company said it had requested a trading halt "changes to foreign investment laws announced last night by the Government and whether an application to the Foreign Investment Review Board is now required in relation to the scheme of arrangement approved by the Supreme Court of Queensland this morning".

Benitec said it expected the trading halt to last until April 1, 2020, or an earlier announcement.

Benitec last traded down 0.1 cents or 3.7 percent to 2.6 cents.

PRO MEDICUS

Pro Medicus says it has bought-back 34,062 shares for $842,962 at prices ranging from $24.18 to $25.70 a share, and will buy-back a further up-to 10,394,683 shares.
Last year, Pro Medicus said it would buy-back up-to 10,361,651 shares or 10 percent of shares on issue during the coming 12 months and had appointed Goldman Sachs Australia Pty Ltd as the broker to buy-back the shares (BD: Apr 2, 2019).
Today, the company said it will buy-back up-to 10 percent of the 10,394,683 shares on issue between April 1, 2020 and March 31, 2021, with Goldman Sachs Australia continuing as the broker.
Pro Medicus was up $1.26 or 6.9 percent to $19.55 with 645,048 shares traded.

BOD AUSTRALIA

Bod says it has launched nine hemp-based products with the Melbourne-based vitamin, supplement and skincare brand, Swisse Wellness.
Bod said the range, which included skincare products and soft gel capsules containing hemp seed oil, would be stocked in about 2,000 locations of retailers including Chemist Warehouse, Coles and Priceline Pharmacy.
Bod was up 2.5 cents or 17.9 percent to 16.5 cents.

LIFESPOT HEALTH

Lifespot has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price rose 305.9 percent from a closing price of 1.7 cents on March 23 cents to a high of 6.9 cents on March 26, 2020 and noted a "very significant increase" in trading volumes.
Lifespot said its announcement on March 25, 2020 which detailed plans to adapt its existing Bodytel smartphone application and platform to include temperature monitoring in response to fever as a symptom of Covid-19 could explain the increase in share price and trading volumes (BD: Mar 25, 2020).
The company restated that it was in discussions on developing a temperature and fever tracking-system to its Bodytel platform and has "ongoing negotiations … with a pharmacy distributor organization".
Lifespot fell 0.6 cents or 9.7 percent to 5.6 cents with 6.8 million shares traded.

IMPEDIMED

has requested a trading halt pending an announcement "regarding the outcome of the institutional component of an accelerated non-renounceable entitlement offer".
Trading will resume on April 3, 2020 or on an earlier announcement.
Impedimed last traded at four cents.

PYC THERAPEUTICS (FORMERLY PHYLOGICA)

PYC has requested a trading halt pending an announcement "regarding results from its lead drug program that [are] material to the company".
Trading will resume on April 1, 2020 or on an earlier announcement.
PYC last traded at six cents.

MICRO-X

Micro-X says it has appointed David Knox as a non-executive director, effective from April 7, 2020, as part of the company's "board rejuvenation process".
Micro-X said Mr Knox was currently the managing-director of Australian Naval Infrastructure and would resign from that position on April 3, 2020.
The company said that Mr Knox previously held executive roles at Santos, BP Developments, Atlantic Richfield Co and Shell.
Micro-X said Mr Knox was currently the chair of Snowy Hydro, the Australian Centre for Social Innovation and a director of the Commonwealth Scientific and Industrial Research Organisation.
Mr Knox held a Bachelor of Science from the University of Edinburgh and a Master of Business Administration from Glasgow's University of Strathclyde.
Micro-X was up one cent or 8.3 percent to 13 cents with 1.6 million shares traded.

GI DYNAMICS

GI Dynamics says non-executive director Timothy Barberich has resigned, effective from March 30, 2020, after nine years with the company.
GI Dynamics was unchanged at 0.3 cents.

RESAPP HEALTH

Resapp says that non-executive director Nathan Buzza has resigned, effective from March 31, 2020.
In 2017, Resapp said it appointed Nathan Buzza as a director, effective from December 29, 2017 (BD: Jan 21, 2018).

ESENSE-LAB

Esense says director Michael Edwards has resigned, having been appointed in November last year (BD: Nov 8, 2019).
Esense was up 0.1 cents or 20 percent to six cents.