Biotech Daily

Tuesday May 5, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: IMUGENE UP 11.5%; OSPREY DOWN 9%**

*** VIVAZOME LICENCES ADELAIDE UNI STEM CELLS FOR EXOSOMES**

*** PHARMAXIS RESUBMITS CYSTIC FIBROSIS BRONCHITOL NDA TO FDA**

*** TBG: CHINA LIFTS EXPORT BAN ON COVID-19 TESTS**

*** MEDICAL DEVELOPMENTS PENTHROX FOR NETHERLANDS, BOSNIA**

*** ELIXINOL 1-FOR-2.51 RIGHTS TO RAISE $11m AT 48% DISCOUNT**

*** RHINOMED REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** G MEDICAL: TGA APPROVES VITAL SIGN MONITOR PATCH**

*** IMPEDIMED APPOINTS DAVID ANDERSON DIRECTOR**

*** MGC STARTS ARTEMIC FOR COVID-19 TRIAL**

MARKET REPORT

The Australian stock market was up 1.64 percent on Tuesday May 5, 2020, with the ASX200 up 87.3 points to 5,407.1 points. Twenty-three of the Biotech Daily Top 40 stocks were up, nine fell, seven traded unchanged and one was untraded. All three Big Caps fell.

Imugene was the best, up 0.3 cents or 11.5 percent to 2.9 cents, with 62.4 million shares traded. Polynovo climbed 11.2 percent; Medical Developments was up 8.6 percent; Dimerix rose 7.3 percent; Oncosil, Opthea and Telix were up more than six percent; Actinogen and Prescient were up five percent or more; LBT, Neuren, Paradigm and Resonance improved four percent or more; Compumedics, Pro Medicus and Proteomics were up more than three percent; Next Science rose 2.5 percent; Avita and Orthocell were up more than one percent; with Clinuvel, Genetic Signatures, Mesoblast and Volpara up by less than one percent.

Osprey led the falls, down 0.1 cents or 9.1 percent to one cent, with 3.4 million shares traded. Uscom fell four percent; Immutep, Kazia and Resmed lost more than three percent; Starpharma shed two percent; Amplia and Ellex were down more than one percent; with Cochlear, CSL, Cynata and Nanosonics down by less than one percent.

VIVAZOME

Vivazome says it has an agreement with the University of Adelaide to collect stem cells from human tissues suitable for the production of subcellular fractions for exosomes.
Vivazome chief executive officer Dr David Haylock told Biotech Daily that “the pro-angiogenic exosomes build blood vessels to increase blood supply and tissue perfusion wherever there is tissue ischemia and cell death - in diseases such as lower limb ischemia which can lead to necrosis and possibly amputations”.
The company said it had licenced stem cell technology from the University of Adelaide, and the agreement covered “the collection of specified tissue types, the selection, derivation and expansion of cell lines from the tissues, and the subsequent supply of those cell lines to Vivazome”.
Vivazome said it would work with the University of Adelaide’s Mesenchymal Stem Cell Laboratory at the School of Medicine to research the licenced technology and develop exosome-based therapeutic products.
The company said that the Laboratory was founded, and led by stem cell researcher Prof Stan Gronthos, a National Health and Medical Research Council principal research fellow with a specialty in stem cell biology and regenerative medicine.
Vivazome said that Prof Gronthos was the co-director of the Centre for Stem Cell Research at the University “and stem cell technology from Prof Gronthos formed part of the founding technology for Mesoblast, the world’s largest stem cell company”.
Dr Haylock said that “based on assessments done at [the Commonwealth Scientific and Industrial Research Organisation] and at La Trobe University, we believe that these cell lines will make pro-angiogenic exosomes with high efficiency”.
“Access to the University’s technology and the associated cell lines is the culmination of an extensive exercise by VivaZome to identify and secure cell types with the potential to function as the factories for our therapeutic exosomes,” Dr Haylock said.
Vivazome is a private company.

PHARMAXIS

Pharmaxis says US licencee Chiesi has resubmitted a US Food and Drug Administration new drug application for Bronchitol for cystic fibrosis.
Last year, Pharmaxis said the FDA required that the Parma, Italy-based Chiesi Farmaceutici SpA revise the product packaging and user instructions and conduct “a human factor study” showing that the revised user components enabled healthcare professionals to properly administer the mannitol tolerance test (BD: Jun 20, 2019).
Today, the company said Cheisi had successfully completed the supplemental human factor study, which involved 45 healthcare professionals in settings simulating a typical mannitol tolerance test environment.
In 2011, Pharmaxis said Bronchitol had been denied European authorization, but after an appeal and resubmission with new data, it was approved and available for sale in Europe by 2012 (BD: May 25, Jun 24, Jul 5, 12, Oct 24, 2011; Apr 20, 2012).
Today, Pharmaxis chief executive officer Gary Phillips said that the company anticipated that the FDA would complete its review in mid-2020 and, if approved, Bronchitol would be made available for US adult cystic fibrosis patients by the end of 2020.
“Steps to prepare our Sydney manufacturing facility to meet US market requirements are already in hand,” Mr Phillips said.
Pharmaxis was unchanged at nine cents.

TBG DIAGNOSTICS

TBG says China has lifted the bans on the export of TGB Biotechnology Xiamen's Covid-19 nucleic acid test kits and it will begin exporting the kits to Europe.
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.
TBG chairman Jitto Arulampalam told Biotech Daily at that time that TBG Xiamen would apply for Chinese approval and was also considering manufacturing the kits outside China (BD: Apr 6, 2020).
On March 17, the company was suspended from the ASX following its share price climbing as much as 27.4 cents or 1,053.8 percent to 30 cents, closing at 27 cents before the trading halt, and on March 18, the company said that TBG Xiamen had Conformité Européenne (CE) Mark approval for the test kits (BD: Mar 17, 18, 2020).
In April, TBG responded to an extended ASX query regarding the company's knowledge of the European approval, the share price rise and the company's subsequent announcement of the approval (BD: Apr 15, 2020).
Today, TBG said that the test kits could be exported from China for sale throughout the European economic area subject to individual countries accepting import of the test kit.
TBG remained in an ASX suspension and last traded at 27 cents.

MEDICAL DEVELOPMENTS

Medical Developments says its Penthrox for emergency relief of moderate to severe pain has been approved for sale in the Netherlands and Bosnia and Herzegovina.
Medical Developments said that the approval process in the Netherlands was part of a set of four countries, including Greece, Hungary and Malta, but of the four only the Netherlands had approved sales.
The company said that Penthrox had not yet achieved government reimbursement in the Netherlands, but sales could be made to the private market.
Medical Developments said that sales approval for Greece, Hungary and Malta was expected "during the course of 2020".
The company said that approval in Bosnia and Herzegovina was a separate process to the European Union approvals, and Penthrox had not been approved for government reimbursement.
Medical Developments was up 61 cents or 8.6 percent to $7.69 with 366,958 shares traded.

ELIXINOL GLOBAL

Elixinol says it hopes to raise $11 million in an institutional and retail one-for-2.51 rights offer at 20 cents a share, a 48.1 percent discount to the last closing price.
Elixinol said shareholders would be able to purchase one new share for every 2.51 shares held.
The company said the funds would be used to support cash flow, consumer brand building and develop distribution networks.
Elixinol said the institutional portion of the offer would open and close on May 5, 2020.
The company said the record date for the retail offer was May 7, with the offer opening on May 12 and closing on May 21, 2020
Elixinol said that Bell Potter Securities was the lead manager of the rights offer.
Elixinol was in a trading halt and last traded at 38.5 cents.

RHINOMED

Rhinomed has requested a trading halt “for the purposes of considering, planning and executing a material capital raising”.
Trading will resume on May 11, 2020 or on an earlier announcement.
Rhinomed last traded at 7.9 cents.

G MEDICAL INNOVATIONS HOLDINGS

G Medical says the Australian Therapeutic Goods Association has approved its vital signs monitoring system extended holter patch.
G Medical said the patch allowed for continuous monitoring of patients at home, as well as hospital outpatient cardiac monitoring.
The company said the patch recorded 14 days of up-to six channel electrocardiogram (ECG) monitoring and could be programmed to send data on request.
G Medical said the device had no wires or extra equipment and enhanced patient compliance, which resulted in more data and improved diagnostics.
The company said the patch allowed for daily showering and had a manual alert button for patients to mark a suspected cardiac event.
G Medical said the patch allowed “for a higher level of patient care … increased efficiency, decreased liability and reduced [the] number of re-admissions”.
In 2017, the company said it had been granted Conformité Européenne (CE) mark certification for its Patch (BD: Nov 30, 2017).
G Medical was up 0.4 cents or 4.3 percent to 9.8 cents with 5.5 million shares traded.

IMPEDIMED

Impedimed says it has appointed David Anderson as a non-executive director.
Impedimed said Mr Anderson was the chief executive officer of Healthnow Systems Inc, operating as Blue Cross Blue Shield health plans in New York State.
The company said that Mr Anderson was a director of the US National Institute of Healthcare Management, the Blue Cross Blue Shield Association, the New York State Business Council and the New York State Insurance Advisory Committee.
The company said Mr Anderson was previously the chief executive officer of Untied Healthcare’s Southern California Health Plan.
Impedimed was unchanged at 3.9 cents with 11.6 million shares traded.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says it has started its 14-day, 50-subject, phase II trial of its supplement artemisinin and curcumin-based Artemic for Covid-19 patients in Israel.
Last month, MGC said it had ethics approval to begin the trial, which would take place at the Nazareth Hospital and the Hillel Yaffe Hospital (BD: Apr 17, 28, 2020).
Today, the company said the trial would evaluate the safety and efficacy of Artemic, a natural immune-modulating formulation, in patients diagnosed with Covid-19.
MGC was unchanged at 2.7 cents with 10.2 million shares traded.