



Biotech Daily

Wednesday December 16, 2020

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: ANTISENSE UP 20%; DIMERIX DOWN 8.5%**
- * **ELLUME: FDA SARS-COV-2 TEST EMERGENCY USE APPROVAL**
- * **MESOBLAST REQUESTS 'CORPORATE UPDATE' TRADING HALT**
- * **TELIX, MUANA KEA PARTNER FOR PROSTATE, KIDNEY CANCER**
- * **TELIX FILES TLX591-CDx PROSTATE IMAGING NDS TO HEALTH CANADA**
- * **AROA: 6-PATIENT MYRIAD '100% HEALING' FOR BONE, TENDON**
- * **IMAGION ENROLMENT OPENS IN MAGSENSE BREAST CANCER TRIAL**
- * **HERAMED, MAYO HERABEAT, HERACARE STUDY**
- * **ELIXINOL PLAN RAISES \$12.3m OF HOPED-FOR \$2m; TOTAL \$20.5m**
- * **SUDA RAISES \$2.76m; ORDESA TERMINATES CO-DEVELOPMENT DEAL**
- * **EMYRIA PLACEMENT RAISES \$1.2m**
- * **OPTISCAN APPOINTS J&H TAIWAN MICROSCOPE DISTRIBUTOR**
- * **RESPIRI: PHARMACY 4 LESS TO SELL WHEEZO ASTHMA MONITOR**
- * **CRESO MARIJUANA DEAL WITH ONTARIO CANNABIS**
- * **CRONOS LAUNCHES HEMP SOAP IN JAPAN, HONG KONG, AUSTRALIA**
- * **THC REQUESTS 'CAPITAL RAISING' TRADING HALT**
- * **CREDIT SUISSE TAKES 7%, CEASES IN DORSAVI**
- * **PERENNIAL BELOW 5% IN IMMUTEP**
- * **DR JOHN MCBAIN, PICTON, 52nd CELEBRATION TAKE 17% OF RHINOMED**
- * **BOD APPOINTS MEDICAL MARIJUANA ADVISORY BOARD**

MARKET REPORT

The Australian stock market was up 0.72 percent on Wednesday December 16, 2020, with the ASX200 up 47.9 points to 6,679.2 points.

Sixteen of the Biotech Daily Top 40 stocks were up, 19 fell and five traded unchanged.

Antisense was the best on no news, up 1.8 cents or 19.6 percent to 11 cents, with 8.5 million shares traded.

Immutep improved 6.2 percent; Next Science climbed 4.3 percent; Cynata, Impedimed and Nova Eye were up three percent or more; Nanosonics, Opthea and Resonance rose more than two percent; Clinuvel, Kazia, Medical Developments, Paradigm, Polynovo, Pro Medicus and Telix were up more than one percent; with Resmed up 0.9 percent.

Dimerix led the falls, down two cents or 8.5 percent to 21.5 cents, with 2.7 million shares traded.

Amplia lost 6.1 percent; Imugene retreated 5.7 percent; Actinogen, Genetic Signatures and Osprey fell more than four percent; Alterity, Oncosil and Universal Biosensors were down more than three percent; Avita, Compumedics and Mesoblast shed more than two percent; CSL, Neuren, Pharmaxis, Prescient and Proteomics were down one percent or more; with Cochlear, Cyclopharm, Starpharma and Volpara down less than one percent.

ELLUME HEALTH

Ellume says it has US emergency use approval for its rapid, at-home severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) antigen test for emergency use. Ellume said the US Food and Drug Administration approval meant that the test would be available for non-prescription home use for the detection of active Sars-Cov-2 in individuals with or without symptoms, and in adults and children aged two years and above.

Last week, Ellume said its rapid, at-home Sars-Cov-2 antigen test was 96 percent accuracy and it had applied for FDA approval (BD: Dec 10, 2020).

Ellume said at that time that pending authorization, the single-use test would be available over-the-counter for \$US30 for symptomatic and asymptomatic detection of Sars-Cov-2 antigen.

Ellume is a public unlisted company.

MESOBLAST

Mesoblast has requested a trading halt "pending an announcement ... in relation to a corporate update".

Trading will resume on December 18, 2020 or on an earlier announcement.

Yesterday, Mesoblast announced mixed results from its seven-year, 537-patient phase III trial of Revascor mesenchymal precursor cells for chronic heart failure saying the stem cells reduced cardiac events, but did not meet the primary endpoint of reducing hospital visits (BD: Oct 31, 2013; Dec 15, 2020).

Mesoblast fell eight cents or 2.1 percent to \$3.77 with 3.4 million shares traded prior to the trading halt.

TELIX PHARMACEUTICALS

Telix says it will collaborate with the Paris-based Mauna Kea Technologies to develop image-guided surgical technologies for prostate and kidney cancer.

Telix said the collaboration would combine its positron emission tomography (PET) tracers that deliver concurrent PET and fluorescent imaging, with Mauna Kea's Cellvizio confocal laser endo-microscopy in-vivo cellular imaging platform".

The company said the Imaging and Robotics in Surgery (Iris) Alliance aimed to provide "real-time visualization of cancer tissues" to urologic surgeons in the operating theatre which could be directly correlated to pre-operative PET imaging.

Telix said the Alliance would develop advanced capabilities for pre-operative planning, intra-operative guidance, surgical margin assessment and other surgical parameters, initially for prostate and kidney cancer.

Telix chief executive officer Dr Christian Behrenbruch said the "techniques our respective companies have developed in molecular targeting and real-time in-vivo cellular imaging have a natural synergy and we are delighted to have formalized this ... partnership".

"Telix and Mauna Kea together aim to deliver significant improvements in surgical techniques and clinical outcomes in patients with urologic malignancies, with the ultimate objective of improving the lives of the patients we serve," Dr Behrenbruch said.

Telix was up five cents or 1.4 percent to \$3.56 with 940,238 shares traded.

TELIX PHARMACEUTICALS

Telix says it has filed a new drug submission with Health Canada for TLX591-CDx for prostate cancer imaging with positron emission tomography (PET).

Telix said it was seeking approval for its TLX591-CDx, or 68-gallium-prostate-specific membrane antigen-11 (68-Ga-PSMA-11), for staging and re-staging of intermediate and high-risk prostate cancer and localizing tumor tissue in recurrent prostate cancer.

Last month, the company said the US Food and Drug Administration has accepted its new drug application for TLX591-CDx (BD: Nov 24, 2020).

Today, the company the said it had submitted marketing applications for TLX591-CDx in Europe, the US, and Australia.

AROA BIOSURGERY

Aroa says a six-patient study of its Myriad had shown a 100 percent healing rate of exposed structures including bone and tendon following surgical reconstruction.

Aroa said Myriad was a perforated, multi-layered extracellular matrix graft, derived from sheep stomach, designed to enable rapid vascularization and build new tissue, for faster healing and recovery.

The company said the study used Myriad in six surgical reconstructions of soft tissue defects with exposed vital structures, with different wound types including full thickness scalp excision, scar revision surgery, tumor removal, traumatic wound, surgical dehiscence, and fistula.

Aroa said that "all patients in the study healed well with a zero rate of complications".

The company said that the study, titled "Extracellular Matrix Graft for Reconstruction Over Exposed Structures: A Pilot Case Series", was published in the Journal of Wound Care and an abstract was available at: <https://bit.ly/3ahxo18>.

Aroa said the results showed the possible use of Myriad in both implant procedures and dermal reconstruction and across a wide range of surgical procedures.

Aroa fell four cents or 3.6 percent to \$1.06.

IMAGION BIOSYSTEMS

Imagion says it has begun enrolment in its phase I imaging study of Magsense for human epidermal growth factor receptor 2 (HER2) metastatic breast cancer. Imagion said Melbourne's Monash Health was the first site in the trial and Monash Health director of breast services Dr Jane Fox would be the principal investigator of the study. The company previously said it expected to conduct the trial at two sites in Melbourne and one in Sydney but has not disclosed the number of patients in the study. Imagion fell 1.5 cents or 10 percent to 13.5 cents with 33.1 million shares traded.

HERAMED

Heramed says the Mayo Clinic has approved a 50-patient study of its Herabeat at-home foetal heart-rate monitor and its Heracare pregnancy management platform. Last year, Heramed said it would partner with the Rochester, Minnesota Mayo Clinic to improve at-home pregnancy care, based on Mayo's OB Nest project, later expanded to develop the Heracare platform (BD: Sep 17, 2019; Jul 21, 2020). Today, the company said the study would review the functionality, usability and user acceptability of the Herabeat device and Heracare platform, as well as an evaluation of the impact of the device on low-risk expectant mothers' perception of foetal wellbeing. The company said the trial would begin this year and be completed in October 2021. Heramed was unchanged at 13 cents.

ELIXINOL GLOBAL

Elixinol says its "significantly over-subscribed" share plan at 17 cents has received applications of \$27.2 million, which has been scaled back to \$12.3 million. Last month, Elixinol said it had raised \$8.2 million in a placement and hoped to raise a further \$2 million through the share purchase plan, which could be increased or scaled back depending on demand (BD: Nov 16, 2020). Today, the company said the scale back of the share plan was on a pro-rata basis, with each applicant allotted a minimum of \$1,500 worth of shares. Elixinol said that participants who applied for less than their pro-rata amount would receive their full amount. The company said Bell Potter Securities and MST Financial Services were joint lead managers to the capital raising. Elixinol was up half a cent or 2.3 percent to 22 cents with 4.8 million shares traded.

SUDA PHARMACEUTICALS

Suda says it has received commitments to raise \$2,761,523 in an "over-subscribed" placement at 3.6 cents a share. Suda said the share price was an eight percent discount to the 10-day volume weighted average price to December 11, 2020. The company said the funds raised would be used for the next 12 months of development and the evaluation of possible acquisitions. Suda said that directors and management could contribute up to \$50,000 of the placement, subject to shareholders' approval of director participation. The company said Baker Young was the lead manager for the placement. Suda fell 0.3 cents or 6.7 percent to 4.2 cents with 3.6 million shares traded.

SUDA PHARMACEUTICALS

Suda says Spain's Ordesa Laboratories has opted not to proceed with the agreement to co-develop a paediatric consumer product using Suda's Oromist technology.

Last year, Suda says it had an agreement the Saint Boi de Llobregat-based Ordesa, in which Ordesa would fully fund a feasibility study and would pay Suda an upfront option fee of \$US100,000 (\$A140,000) to use its Oromist technology (BD: Dec 5, 2019).

Today, Suda managing-director Dr Michael Baker said that company had "enjoyed working with Ordesa on this challenging project".

"We look forward to keeping the discussions open between the two groups to assess if there are other products that may benefit from being converted into an oral spray," Dr Baker said.

EMYRIA (FORMERLY EMERALD CLINICS)

Emyria says it has raised \$1.2 million in an "over-subscribed" placement at 8.5 cents a share, including one free option for every three shares purchased.

Emyria said the share price was equal to its last closing share price and the free attaching options would be exercisable at 20 cents each within two years.

The company said the funds would be used for trials of its marijuana-based EMD-003 for mental health and EMD-004 for irritable bowel syndrome.

Emyria said the Perth-based Sixty Two Capital was the lead manager and cornerstone investor of the placement, investing \$500,000.

Emyria was up 0.1 cents or 1.2 percent to 8.6 cents with three million shares traded.

OPTISCAN

Optiscan says it has appointed J&H Technology Co to distribute its Five2 hand-held confocal endo-microscope within the pre-clinical research market in Taiwan.

Optiscan executive chair Darren Lurie said the appointment of the Taipei-based J&H continued the expansion of international distribution arrangements for the Five2, or Viewnivo, in the pre-clinical research market.

Optiscan was unchanged at 11.5 cents.

RESPIRI

Respiri says its Wheezo device for asthma management will be sold at Pharmacy 4 Less retail shops across Australia from "early 2021".

Respiri said Pharmacy 4 Less had more than 100 shops across Australia.

Respiri was up one cent or eight percent to 13.5 cents with 1.3 million shares traded.

CRESO PHARMA

Creso says it will supply its Ritual Green brand recreational marijuana products to Canada's Ontario Cannabis Retail Corporation, trading as Ontario Cannabis Store.

Creso said the agreement was made through its wholly-owned subsidiary Mernova Medical Inc.

The company said Ritual Green brand products, HPG13, Lemon Haze and Mimosa, would be sold through Ontario Cannabis' stores as well as online sales platform.

Creso said that the sales order volume commitments were "yet to be finalized".

Creso fell 1.5 cents or 6.4 percent to 22 cents with 39.5 million shares traded.

CRONOS AUSTRALIA

Cronos says it has “soft” launched its Bathing Shed brand range of hemp seed oil-based soap in Japan, Hong Kong and Australia.

Cronos said that the Bathing Shed brand was developed by its Hong Kong-based subsidiary, Personal Care Asia.

The company said it planned a broader official launch of the range in 2021.

Cronos was up 1.5 cents or 11.5 percent to 14.5 cents.

THC GLOBAL

THC had requested a trading halt pending an announcement “with respect to capital raising activities”.

Trading will resume on December 18, 2020 or on an earlier announcement.

THC last traded at 27 cents.

DORSAVI

In separate substantial shareholder notices, Credit Suisse says it has increased its holding in Dorsavi to 21,675,871 shares (7.26%) and then reduced below five percent.

Credit Suisse said it bought and sold shares on December 11, 2020, acquiring 5,895,267 shares for \$380,054 or 6.4 cents a share.

In a second notice, Credit Suisse said that on December 14, it bought a further 1,140,468 shares for 60,362 or 5.3 cents a share and sold 14,272,319 shares for \$926,510 or 6.5 cents a share.

Biotech Daily calculates that Credit Suisse holds 8,544,020 shares or 2.86 percent of Dorsavi.

Dorsavi was up 0.1 cents or 2.3 percent to 22 cents with 4.8 million shares traded.

IMMUTEP

Sydney’s Perennial Value Management says it has ceased its substantial shareholding in Immutep following a dilution.

Last month, Immutep said it has raised \$29.6 million in placement at 24 cents a share, with Perennial listed as a major investor (BD: Nov 19, 2020).

Perennial did not file a becoming substantial shareholder notice prior to its ceasing substantial notice and did not specify how many shares it held or sold in Immutep.

Immutep was up 2.5 cents or 6.2 percent to 43 cents with 9.1 million shares traded.

RHINOMED

Dr John McBain, Picton Cove and Fifty-Second Celebration say they have increased their holding in Rhinomed from 41,315,538 shares (16.28%) to 44,195,270 shares (17.41%)

The Melbourne-based Dr McBain said that between November 13 and December 15, 2020 Fifty-Second and Picton acquired 2,879,732 shares for \$509,855 or an average of 17.7 cents a share.

Rhinomed was unchanged at 19 cents.

[BOD AUSTRALIA](#)

Bod says it has appointed Prof Iain McGregor, Prof Arman Sabet, Prof Andrew McLachlan and Prof Ian Olver as advisors following the cannabidiol re-classification.

Yesterday, the Australia Therapeutic Goods Administration said it had down-scheduled low-dose cannabidiol (CBD) products containing up to 150mg/day, from schedule 4 (prescription medicine) to schedule 3 (pharmacist only medicine), allowing low-dose CBD to be sold over-the-counter (BD: Dec 15, 2020).

Today, Bod chief executive officer Jo Patterson said that the TGA decision “marks a major step forward for the sale of CBD in Australia and we are very confident that the establishment of our medical advisory board leaves the company very well placed to capitalize”.

The company said Prof McGregor was a director of the Lambert Initiative for Cannabinoid Therapeutics, Prof Sabet was the head of neurology at the Gold Coast University hospital, Prof McLachlan was the dean of Sydney Pharmacy School and Prof Olver was the former chief executive officer of the Cancer Council.

Bod fell half a cent or 0.9 percent to 55.5 cents.