



Biotech Daily

Monday February 8, 2021

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: OPTISCAN UP 18%; ACTINOGEN DOWN 15%**
- * **OPTISCAN STARTS BREAST CANCER MARGIN MICROSCOPE STUDY**
- * **CANN GROUP: \$3.6m 'CYBER SECURITY INCIDENT'**
- * **PROTEOMICS FILES FDA PROMARKERD PRE-SUBMISSION**
- * **TELEX TERMINATES PI MEDICAL NETHERLANDS DISTRIBUTION**
- * **HERAMED: SHEBA HERABEAT FOETAL HEART MONITOR TRIAL**
- * **ANATARA READY FOR GARP IBS DIARRHOEA TRIAL**
- * **LITTLE GREEN: 1st GERMAN COMMERCIAL MARIJUANA SHIPMENT**
- * **CRESO TAKES-BACK SWISS MARIJUANA DISTRIBUTION**
- * **RESPIRI: PHARMACY CATALYST TO SELL WHEEZO ASTHMA MONITOR**
- * **EXOPHARM PLEADS SCHULTZ TO ASX 30% QUERY**
- * **STEMCELL PLEADS SCHULTZ TO ASX 59% QUERY**
- * **AVECHO REQUESTS CAPITAL RAISING HALT**
- * **MEDIBIO REQUESTS CAPITAL RAISING HALT**
- * **ANGLO AUSTRALIAN CHRISTIAN DILUTED TO 14% IN CYCLOPHARM**
- * **PERENNIAL HOLDS 12% OF MICRO-X**
- * **REGAL FUNDS TAKES 10% OF ELIXINOL**
- * **MCRAE DILUTED TO 27% IN NEUROSCIENTIFIC**
- * **ACTINOGEN LOSES 6-YEAR CEO DR BILL KETELBEY**
- * **RACE APPOINTS MARY HARNEY DIRECTOR**
- * **NEALE JAVA TO REPLACE CONTROL BIONICS CFO JOHN BELL**

MARKET REPORT

The Australian stock market climbed 0.59 percent on Monday February 8, 2021, with the ASX200 up 40.2 points to 6,880.7 points. Fifteen of the Biotech Daily Top 40 stocks were up, 22 fell and three traded unchanged.

Optiscan was the best, up two cents or 18.2 percent to 13 cents, with 3.1 million shares traded. Mesoblast, Orthocell, Osprey, Proteomics and Telix climbed more than four percent; Uscom was up 3.3 percent; Genetic Signatures, Imugene and Starpharma rose more than two percent; Amplia, Immutep and Pharmaxis were up more than one percent; with Clinuvel, CSL and Pro Medicus up by less than one percent.

Friday's 28.6 percent best on no news, Actinogen, fell 0.4 cents or 14.8 percent to 2.3 cents with 51.4 million shares traded, on the loss of six-year CEO Dr Bill Ketelbey. Antisense lost 7.3 percent; LBT, Medical Developments, Prescient and Universal Biosensors fell more than four percent; Compumedics, Patrys and Volpara lost three percent or more; Alterity, Nanosonics, Nova Eye, Neuren, Polynovo and Resonance shed more than two percent; Avita, Cyclopharm, Cynata, Dimerix, Next Science and Resmed were down more than one percent; with Cochlear, Opthea and Paradigm down by less than one percent.

OPTISCAN IMAGING

Optiscan says it has begun a 20-patient "stage three" of its study of its confocal microscope for breast cancer in Melbourne.

In 2018, Optiscan began the first part of the trial of its confocal microscope technology to assess the surgical margin in patients undergoing breast cancer conservation surgery (BD: Oct 15, 2018).

The company said at that time that the lumpectomy trial would be conducted at the Perth, Western Australia-based Hollywood Private Hospital, with the goal "to assist both breast surgeons and pathologists to provide real-time determination of the required surgical margin - reducing the risk of residual tumor, the need for repeat surgery and the associated emotional distress suffered by the patients".

Optiscan said in 2018 that if the goals were achieved they would have a "significant positive impact for patient welfare as well as substantially reducing the number of repeat operations and reducing associated costs for the patients, hospitals, insurers and the taxpayer".

Today, the company said the study would be conducted by surgeon Prof Bruce Mann at the Royal Melbourne Hospital, the Royal Women's Hospital's Frances Perry House and the private Epworth Hospital using its Five2, or Viewnivo, endo-microscope.

Optiscan said that the hand-held endo-microscope enabled real-time, three-dimensional imaging of human tissue at the cellular level, "reducing or eliminating the need to have specimens sent to a laboratory for processing".

"By ensuring that we achieve clear or negative margins at initial surgery, we expect to reduce the requirement for a second surgery, which currently occurs in over 20 percent of lumpectomy cases," Prof Mann said.

Optiscan said that freshly excised tissue would be immediately imaged before it was sent to pathology for histopathological processing and analysis to determine if all the tumor had been removed.

The company said the trial was supported by the Medical Device Partnering Program.

Optiscan was up two cents or 18.2 percent to 13 cents with 3.1 million shares traded.

CANN GROUP

Cann Group says it has had “a cyber security incident, involving an unknown third party” resulting in a \$3.6 million missing payment to an overseas contractor.

Cann said the incident was discovered overnight on Thursday February 4, 2021 and was under investigation.

On Friday, the company requested a trading halt pending an announcement “relating to an investigation that the company is undertaking” (BD: Feb 5, 2021).

Today, Cann Group said it recently made payments of about \$3.6 million to an unnamed overseas contractor in relation to works being undertaken for its Mildura facility, but “those payments have been received by an unknown third party as a result of a complex and sophisticated cyber fraud perpetrated against the company and its overseas contractor”. The company said it was working with its bank to determine if any of the payments could be halted and if any of the funds involved were recoverable.

Cann Group said it had notified its insurance brokers to determine if a claim could be made to recover any of the losses involved.

The company said that immediate action had been taken to ensure the integrity of its information technology (IT) systems.

Cann said it was in a financial position to continue with its ongoing operations and projects, including the construction of its Mildura facility, irrespective of any funds being recovered.

The company said that with its overseas contractor it was investigating the incident, including engagement of external security and forensic information technology experts.

Cann Group said that the matter had been reported to police in Victoria, Australia, the Netherlands and Hong Kong, as well as the Office of Drug Control.

Cann Group was unchanged at 66 cents with 5.7 million shares traded.

PROTEOMICS INTERNATIONAL

Proteomics says it has filed a pre-submission package to the US Food and Drug Administration for its Promarkerd test for diabetic kidney disease.

Proteomics said it expected to meet the FDA within 10 weeks to progress clearance and it would provide peer-reviewed clinical performance data showing effectiveness of the test, including a 3,000-patient study.

Last year, the company said it had Conformité Européenne (CE) mark approval for its Promarkerd immunoassay as an in-vitro diagnostic for kidney disease onset in type 2 diabetes patients (BD: Apr 16, 2020).

Today, the company said the FDA pre-submission allowed manufacturers of innovative diagnostics and medical devices to discuss specific aspects of the regulatory process and requirements with FDA experts.

Proteomics said the process would determine the regulatory path forward for Promarkerd as either de-novo classification or the 510(k) pre-market approval route.

Proteomics managing-director Dr Richard Lipscombe said FDA approval “would be a significant commercialization milestone for Promarkerd”.

“FDA sign-off would assure potential licencing partners and consumers that the test has been developed and manufactured to US safety, health and environmental protection standards,” Dr Lipscombe said.

“With CE mark approval and FDA clearance we would have access to more than 70 percent of the global [in-vitro] diagnostic market,” Dr Lipscombe said.

Proteomics said it would seek additional regulatory approvals for its Promarkerd kit.

Proteomics was up 3.5 cents or 4.6 percent to 80 cents.

TELIX PHARMACEUTICALS

Telix says it has terminated its agreement with PI Medical for distribution of TLX591-CDx, or Illuccix, prostate cancer imaging kits in Netherlands and Belgium.

Telix said it had developed a suitable network, production infrastructure and commercial team to distribute TLX591-CDx or 68-gallium-prostate-specific membrane antigen-11 (68-Ga-PSMA-11) to distribute its own products in the Netherlands and it had “invested heavily in its European footprint” which included last year’s acquisition of the Seneffe, Belgium-based radio-pharmaceuticals manufacturing facility (BD: Apr 3, 2020).

Today, Telix said the contract with PI Medical Diagnostic Equipment BV included non-exclusive distribution rights in the Flemish region of Belgium.

Telix European head Ludovic Wouters said the company had “built a very capable commercial team ... [at its] Belgium headquarters and established strong clinical relationships in the Netherlands, Belgium and Luxembourg”.

“This decision leverages the talent of the team and ensures the closest possible working relationship with some of our most important clinical sites in Europe,” Mr Wouters said.

Telix was up 18 cents or 4.3 percent to \$4.37 with 429,495 shares traded.

HERAMED

Heramed says Tel Aviv’s Sheba Medical Centre has begun a pilot program testing its Herabeat foetal heart rate monitor and its Heracare platform for telehealth.

Heramed said the program, with an undisclosed number of patients, would begin with pregnant women admitted to its Covid-19 unit and requiring continuous monitoring.

The company said the second stage would involve high-risk and post-term pregnancies in which constant and real-time remote pregnancy monitoring was necessary.

Heramed said Sheba was Israel’s largest hospital and cared for about 1.6 million people. Heramed was unchanged at 10.5 cents.

ANATARA LIFESCIENCES

Anatara says it has ethics approval for a 200-patient trial of the pineapple stem bromelain-based complementary medicine for irritable bowel syndrome with diarrhoea.

Last December the company said it expected to begin a randomized, controlled trial for irritable bowel syndrome in early 2021 having previously hoped it would begin by December 31, 2020 (BD: Jun 23, Dec 8, 2020).

Anatara chief executive officer Steve Lydeamore told Biotech Daily in December that the bromelain-based gastro-intestinal re-programming (Garp) product included bromelain and other components which were safe and had been shown to have efficacy for gut health. Today, the company said that patient recruitment was planned for March 2021 and it would be conducted in two stages as a virtual study involving “minimal on-site visits and participants completing most assessments online”.

Anatara said that up-to six sites would be established with an interim analysis between stage 1, which would assess safety, tolerability and efficacy of two different strengths of Garp against placebo and stage 2 comparing the chosen dose to placebo.

The company said that each participant would be studied for 12 weeks; including two weeks screening and baseline measurement, eight weeks of treatment and a two-week washout period.

Anatara said measurements would include surveys of the severity scoring system, quality of life, adequate relief and the Bristol stool form scale.

Anatara was unchanged at 20 cents.

LITTLE GREEN PHARMA

Little Green Pharma says it has exported the first commercial shipment of cannabis flower medicines to Deutsche Medizinalcannabis GmbH (Demecan) in Germany.

Little Green said the initial shipment consisted of 500 units of 15g high-tetra-hydro-cannabinol (THC) medicines and would be batch-tested on arrival in Germany next week. The company said that under the three-year agreement it would export up to 1,000kg or 48,000 units of its products a year.

Little Green was untraded at 93.5 cents.

CRESO PHARMA

Creso says it will take back the distribution, marketing and sales of its marijuana product Cannaqix from its commercial partner Doetsch Grether in Switzerland.

Creso said it had wholesalers reaching more than 2,100 pharmacies and drugstores as point-of-sales to consumers and it would directly supply to all those major wholesalers in Switzerland

Creso fell half a cent or 2.4 percent to 20.5 cents with 21.8 million shares traded.

RESPIRI

Respiri says Pharmacy Catalyst will sell its Wheezo asthma monitor beginning in March. Respiri said Pharmacy Catalyst had 350 members and pharmacists would work with asthma patients to review their conditions, making any recommendations and including Wheezo to improve patient management.

The company said that Pharmacy Catalyst was a member of Pharmacy Platform Pty Ltd, an entity combining Advantage Group and Instigo.

Respiri fell half a cent or four percent to 12 cents with 1.2 million shares traded.

EXOPHARM

Exopharm 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 30.3 percent from 61 cents on February 5 to 79.5 cents on February 8, 2021 and noted a "significant increase" in trading volume.

Exopharm was up 21 cents or 34.4 percent to 82 cents with six million shares traded.

STEMCELL UNITED

Stemcell 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 58.8 percent from 1.7 cents to 2.7 cents between February 5 and 8 2021 and noted a "significant increase" in trading volume.

Stemcell was up 0.4 cents or 20 percent to 2.4 cents with 166.7 million shares traded.

AVECHO BIOTECHNOLOGY (FORMERLY PHOSPHAGENICS)

Avecho has requested a trading halt pending the release of information "relating to a capital raise".

Trading will resume on February 10, 2021 or on an earlier announcement.

Avecho last traded at 2.7 cents.

MEDIBIO

Medibio has requested a trading halt pending an announcement “regarding a capital raise”.

Trading will resume on February 10, 2021 or on an earlier announcement.

Medibio last traded at 0.9 cents.

CYCLOPHARM

Anglo Australian Christian and Charitable Fund says its 13,211,332 share-holding in Cyclopharm has been diluted from 16.89 percent to 14.39 percent.

The London-based Anglo Australian Christian and Charitable Fund said it had been diluted on February 1, 2021 following the \$30 million placement (BD: Jan 27, 2021).

Cyclopharm fell four cents or 1.4 percent to \$2.76.

MICRO-X

Perennial Value Management says it has increased its substantial shareholding in Micro-X from 43,887,744 shares (12.21%) to 54,997,171 shares (12.24%).

The Sydney-based Perennial said that it bought and sold shares between December 7, 2020 and February 5, 2021, with the single largest purchase 6,865,757 shares for \$2,403,015 or 35 cents a share.

On February 1, Micro-X said it had raised \$30.5 million in a placement at 34 cents a share and hoped to raise a further \$2.5 million in a share plan (BD: Feb 1, 2021).

Micro-X was unchanged at 35 cents.

ELIXINOL GLOBAL

Regal Funds says it has increased its substantial shareholding in Elixinol from 26,064,192 shares (8.32%) to 31,861,564 shares (10.17%).

The Sydney-based Regal Funds Management Pty Ltd said it bought and sold shares between January 15 and February 3, 2021 with the single largest purchase of 2,662,498 shares for \$524,778 or 19.7 cents a share.

Elixinol was up three cents or 14.6 percent to 23.5 cents with 8.4 million shares traded.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

McRae Investments Pty Ltd says its substantial 24,343,954 share-holding in Neuroscientific has been diluted from 31.1 percent to 26.9 percent.

The Cottesloe, Western Australia McRae Investments said it was diluted on November 16, 2020 and February 5, 2021, following the exercise of options and a placement.

Neuroscientific was unchanged at 22.5 cents.

ACTINOGEN MEDICAL

Actinogen says that Dr Bill Ketelbey has resigned as its chief executive officer and as a director, effective today.

Actinogen said it thanked Dr Ketelbey “for his considerable and valued services and contribution ... over the past six years”.

The company said that chair Dr Geoff Brooke would be the interim executive chair.

Actinogen fell 0.4 cents or 14.8 percent to 2.3 cents with 51.4 million shares traded.

RACE ONCOLOGY

Race says it has appointed Mary Harney as a non-executive director.

Race said Ms Harney was currently the director of consulting firm, Mary Harney Advisory and chair of the privately-owned CTx One Pty Ltd.

The company said Ms Harney was formerly the Royal Australasian College of Surgeons chief executive officer, Gardiner Research Foundation chief executive officer and Peter MacCallum Cancer Centre chief operating officer and director of the office of cancer research.

Race said Ms Harney held a Bachelor of Science from Melbourne's Monash University and a Bachelor of Arts from the University of Melbourne.

Race fell 12 cents or 4.8 percent to \$2.36 with 3.9 million shares traded.

CONTROL BIONICS

Control Bionics says it has appointed Neale Java as its chief financial officer, replacing John Bell.

Control Bionics said that its current chief financial officer John Bell would remain with the company until April 1, 2021 and be responsible for completion of the half year accounts ended December 31, 2020.

The company said that Mr Java would assume full responsibilities from March 1, 2021 and have operational responsibilities for Australia and the US.

Control Bionics said that Mr Java had 15 years' experience "in driving the growth and profitability agendas of businesses and spearheading corporate development".

The company said that Mr Java held a Bachelor of Electrical Engineering from the University of Wollongong, a Master of Applied Finance from Macquarie University and an Executive Master of Business Administration from the Paris-based Institut Européen d'Administration des Affaires (Insead).

Control Bionics fell five cents or 6.6 percent to 71 cents.