



Biotech Daily

Monday December 7, 2020

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: OPTISCAN UP 12.5%; ONCOSIL DOWN 11%**
- * **DOHERTY'S DR SIMONE PARK WINS \$20k VICTORIA PREMIER'S AWARD**
- * **TGA PRIORITY REVIEW FOR TELIX PROSTATE CANCER IMAGING TLX591-CDX**
- * **CSIRO, ANATOMICS COLLABORATE ON SMART HELMET FOR SEIZURES**
- * **MESOBLAST: BIOMARKERS BACK REMESTEMCEL-L FOR GVHD**
- * **LIFESPOT 1-FOR-4 RIGHTS ISSUE FOR \$2.4m**
- * **MEDADVISOR: H2 ADHERIS REVENUE UP 14.5% TO \$21m**
- * **NEUREN: 'EMA POSITIVE OPINIONS FOR ORPHAN STATUS'**
- * **NOXOPHARM FINDS HARD-TO-TREAT CANCER CANDIDATES**
- * **CANN GLOBAL REQUESTS 'CAPITAL RAISING' TRADING HALT**
- * **AZURE APPLIES FOR TOCOTRIENOL DELIVERY PATENT**
- * **ATOMO: PREP HEALTH DISTRIBUTES HIV SELF-TEST; EASE OF USE STUDY**
- * **UNIVERSAL BIOSENSORS: GRAPEWORKS AUSTRALIA SENTIA DISTRIBUTOR**
- * **EMVISION RELEASES 16.8m ESCROW SHARES**
- * **COGSTATE APPOINTS DARREN WATSON CFO, BEN BLOOMFIELD CTO**

MARKET REPORT

The Australian stock market was up 0.62 percent on Monday December 7, 2020, with the ASX200 up 40.9 points to 6,675.0 points. Seventeen of the Biotech Daily Top 40 stocks were up, 15 fell and eight traded unchanged.

Optiscan was the best, up 1.5 cents or 12.5 percent to 13.5 cents, with 3.97 million shares traded. Neuren climbed 6.4 percent; Actinogen, Amplia, Compumedics and Medical Developments improved more than four percent; Alterity, Immutep, Mesoblast, Next Science and Resonance were up more than three percent; Nanosonics, Nova Eye, Pharmaxis and Polynovo rose more than two percent; Proteomics was up 1.6 percent; with CSL, Pro Medicus and Resmed up by less than one percent.

Oncosil led the falls, down 1.5 cents or 10.7 percent to 12.5 cents, with 10.9 million shares traded. Paradigm lost 7.4 percent; Impedimed was down 6.7 percent; Universal Biosensors and Uscom were down more than five percent; Opthea fell 4.5 percent; Cochlear, Dimerix and Telix were down more than three percent; Orthocell shed 2.35 percent; Avita, Cyclopharm, Cynata, Prescient and Starpharma were down more than one percent; with Clinuvel down by 0.9 percent.

VICTORIA GOVERNMENT

The Victoria Government says the Peter Doherty Institute's Dr Simone Park has won the \$20,000 Premier's Research Excellence Award.

A media release from the Minister for Innovation, Medical Research and the Digital Economy Jaala Pulford said that Dr Simone Park won the award "for her work on local immune protection against cancer and infection".

The State Government said that Dr Park's research showed "how local immune cells inhibit cancer and infection, with encouraging evidence for further exploration of tissue-resident memory cells as targets of future cancer therapy and vaccines".

The media release said that Dr Park also was awarded a trophy designed by Geelong-based Indigenous art collective Wathaurong Glass.

The Victoria Government said other finalists for the Premier Awards conducted research into the genetic factors in cancer risk, managing health risks in babies, finding gentler approaches to diagnosing young children, time-critical treatment of stroke patients, influences in mental health vulnerability and treatment and targeted treatment of chronic health issues.

The media release said that the category winners would each receive \$5,000.

The Government said the finalists were Monash University's Cammi Murrup-Stewart, University of Melbourne and Murdoch Children's Research Institute Dr Melissa Lee, and the University of Melbourne's Dr Xinyang Hua and Dr Jesse Young.

"Victorian researchers improve lives and save lives with their hard work, inspiration and sustained excellence, and that's why we back them every step of the way," Ms Pulford said.

TELIX PHARMACEUTICALS

Telix says the Australian Therapeutic Goods Administration has granted priority review status for its prostate cancer imaging product TLX591-CDx.

Telix said TLX591-CDx, or 68-gallium-prostate specific membrane-11 (68Ga-PSMA-11) was a radiopharmaceutical for the imaging of prostate cancer using positron emission tomography (PET).

The company said the priority review gave it a "significantly accelerated timeframe of 150 working days for product dossier review and approval".

Telix said it applied to the TGA at the same time as filing its new drug application to the US Food and Drug Administration, the first commercial new drug application for PSMA imaging in the US, "a major commercial milestone" following its European submission in April 2020 (BD: May 1, Nov 24, 2020).

The company said that an Australian Medical Services Advisory Committee application was in progress and it expected that approval and commercial availability of TLX591-CDx should coincide about May to June of 2021, subject to TGA review and approval.

Telix chief executive officer Dr Chris Behrenbruch said that "as an Australian headquartered company, we are especially delighted that the TGA has granted priority review for TLX591-CDx, bringing us one step closer to providing a commercially available prostate imaging agent to patients in our own backyard".

"This is an important development for urologic oncology in Australia as a properly validated and commercially available product will ensure far greater patient access and confidence in the technology, currently only available on a limited basis under special access use from a relatively small number of academic nuclear medicine departments around the country," Dr Behrenbruch said.

Telix fell 12 cents or three percent to \$3.83 with 1.3 million shares traded.

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The CSIRO says its staff have developed implantable devices equipped with machine learning to help prevent seizures and monitor patients after brain surgery.

The CSIRO said that with a \$1 million Federal Government grant to Melbourne's Anatomics it would develop a 'smart helmet' to monitor brain swelling in stroke and traumatic brain injury patients.

The Organisation's Data61 researcher Dr Umut Guvenc said that traumatic brain injuries affected more than 69 million people worldwide, including 700,000 Australians, with one in three likely to develop chronic epilepsy due to the high frequency of seizures.

"Monitoring brain activity post-surgery is especially critical to a patient's recovery as seizures can regularly occur, often leading to patients developing epilepsy," Dr Guvenc said.

"These seizures are often difficult to detect, with current monitoring techniques only able to be used in a hospital using bulky devices for less than 24 hours, providing a brief snapshot of brain activity during that time only," Dr Guvenc said.

"This new method can continuously monitor brain activity wirelessly, allowing the patient to be mobile, comfortable and more socially active," Dr Guvenc said.

The CSIRO said that the machine learning was trained using data from Monash University and could detect "even the smallest seizures before transferring the data securely from the helmet to the healthcare practitioner".

The Organisation said that during normal brain activity, the implants remained in standby mode to conserve energy while monitoring brain activity for seizures and were reactivated when a seizure is detected, sampling the signal at higher resolution.

Data61 senior research engineer Peter Marendy said the project aimed to use the insights from the helmets to develop a 'brain machine interface', enabling clinicians to monitor brain function in real-time.

"Information provided by the implants can be used to inform clinicians about the patient's brain activity and inform decisions regarding the administering of drugs," Mr Marendy said.

"The combination of brain swelling, surgery timing and patient outcome data will enable further study on the ideal time to perform a reconstructive cranioplasty to achieve the best patient outcome, research that will ultimately influence future medical decisions," Mr Marendy said.

Anatomics research and development fellow Dr Ganesha Thayaparan said the collaboration had produced "a number of medical world-firsts, including additively manufactured patient-specific titanium implants".

"The smart helmet project builds upon our existing Skullpro technology to develop a remote sensing platform to monitor the injured brain following a decompressive craniectomy," Dr Thayaparan said.

The CSIRO said the development of the technologies was enabled by its Probing Biosystems Future Science Platform, which provided initial funding to support the research.

The Organisation said the work brought together cross-domain experts from across CSIRO, including energy and mineral resources researchers who were developing the micro batteries used in the implants.

For more information, project updates, or to collaborate, go to:

<https://research.csiro.au/cybernetics/brain-implants/>.

MESOBLAST

Mesoblast says it has biomarker evidence linking remestemcel-L's immune-modulatory activity to survival outcomes in children with acute graft-versus-host disease (GvHD). Mesoblast said data from its pivotal trial of mesenchymal stem cell product, remestemcel-L, for steroid-refractory acute graft-versus-host disease was presented at the American Society of Hematology meeting by lead investigator and Duke University Medical Centre transplant physician Dr Joanne Kurtzberg (BD: Feb 20, 2020).

The company said that "clinically meaningful overall responses and survival in children with [steroid-refractory acute] GvHD treated with remestemcel-L were associated with significant reductions in certain biomarkers of inflammation which have been validated as predictors of mortality risk".

Mesoblast said the durable reductions in blood levels of certain biomarkers associated with inflammatory diseases of the gut suggested that these could be more generally reflective of remestemcel-L activity in other inflammatory bowel diseases such as Crohn's disease and ulcerative colitis.

The company said that blood levels of soluble suppression of tumorigenicity 2 (ST2) and Magic biomarker score (MBS), validated biomarkers that predicted high mortality in steroid-refractory acute graft-versus-host disease and active gut inflammation more broadly, were measured at baseline and sequentially over 180 days in 40 of the 54 children, received at least four weeks of remestemcel-L treatment in the single-arm phase III trial.

Mesoblast said that both the elevated baseline levels of ST2 and MBS were significantly reduced after remestemcel-L treatment at days 100, 160 and 180 (all timepoints $p < 0.001$ for both markers).

The company said that the children had "significant reductions in activated circulating T-cells".

Mesoblast said that day-100 survival was 74 percent in the 54 remestemcel-L children with graft-versus-host disease, of which 89 percent had grade C/D disease, which compared "very favorably with a mortality approaching 70 to 90 percent in children of similar severity treated with other therapies".

Dr Kurtzberg said the results "support the bioactivity of remestemcel-L in treating the severe inflammation in children with acute graft versus host disease refractory to steroids and provide evidence linking the immunomodulatory properties of remestemcel-L with the excellent responses and survival we see when treating these desperately ill children".

Mesoblast was up 17 cents or 3.9 percent to \$4.49 with 8.4 million shares traded.

LIFESPOT HEALTH

Lifespot says it hopes to raise \$2,358,536 through a non-renounceable, one-for-four rights issue at seven cents a share.

Lifespot said the funds would be used to further the development plans for its Bodytel health monitoring and medicine delivery software platform for chronic diseases.

The company said the record date would be December 10, the offer would open on December 14 and close on December 24, 2020.

Lifespot said it previously raised \$1,680,500 in a placement to MID Wealth Pty Ltd and Cannvalate Pty Ltd to fund trials of its Medihale inhaler and other cannabinoid inhalational devices, complete the final stages of a Bodytel Fevertel workplace product and marketing of the Fevertel home and workplace products (BD: Nov 4, 2020).

Lifespot fell 1.1 cents or 12.4 percent to 7.8 cents.

MEDADVISOR

Medadvisor expects that revenue from its Adheris US subsidiary for the six months to December 31, 2020 will be up 14.5 percent to \$US15.8 million (\$A21.3 million). Medadvisor said it acquired Adheris in November with revenue for the six months expected to be \$US13.8 million, but had exceeded that (BD: Nov 12, 2020). The company said the full-year forecast was revised up 7.5 percent to \$US28.4 million. Medadvisor was unchanged at 39 cents.

NEUREN PHARMACEUTICALS

Neuren says the European Medicines Agency has provided positive opinions on orphan status applications for Phelan-McDermid, Angelman and Pitt Hopkins syndromes. In September, Neuren submitted the orphan drug designation applications to European Medicines Agency (BD: Sep 29, 2020). Last year, the company said the US Food and Drug Administration had granted it orphan status for all three indications (BD: Oct 11, 16, 2019). Today, Neuren said that formal decisions were expected in January 2021. The company said European Union orphan designation enabled sponsors “to benefit from incentives including free protocol assistance, fee reductions and 10 years of market exclusivity plus two additional years if approved for paediatric use”. Neuren said during the exclusivity period, the European Medicines Agency and European Union member states would not accept another marketing authorization application for similar medicinal products with the same therapeutic indication. The company said it planned to begin its phase II trials next year in the three syndromes “to confirm the potential of NNZ-2591 to address the urgent unmet need in these three serious childhood disorders”. Neuren chief executive officer Jon Pilcher said the company was “pleased to have received no questions following the EMA review of our compelling pre-clinical results and the rationale for treatment with NNZ-2591”. “We move forward to phase II trials with increased confidence now that we have orphan designation for all three indications in the two largest markets,” Mr Pilcher said. Neuren was up 7.5 cents or 6.4 percent to \$1.255.

NOXOPHARM

Noxopharm says it has identified a “series of small molecules that are highly active against hard-to treat cancer types such as ... pancreatic, gallbladder and liver cancers”. Noxopharm said the compounds showed “substantial resistance to phase two metabolism, a process designed to clear drugs from the body but which can lead to considerable loss of anti-cancer function”. Noxopharm chief executive officer Dr Graham Kelly said “the discovery has led to the creation of molecules capable of killing chemo-resistant pancreatic and gallbladder cancer cells, while remaining protected from phase two metabolism”. “That dual effect of creating a drug with potent anti-cancer function at the same time as protecting against loss of that potency once in the body is what is so exciting after so many years of research,” Dr Kelly said. The company said it hoped to identify its lead candidate soon, pre-clinical testing would take about 15 months, with the first-in-human pharmaco-kinetic study in Australia in mid-2022, and it had begun preparing a patent application to cover the discovery. Noxopharm was up 1.5 cents or 2.5 percent to 60.5 cents with 3.5 million shares traded.

CANN GLOBAL

Cann Global has requested a trading halt “pending the release of an announcement regarding a proposed capital raising”.

Trading will resume on December 9, 2020 or on an earlier announcement.

Cann Global last traded at 0.6 cents.

AZURE HEALTH TECHNOLOGY

Azure says it has lodged an Australian patent application relating to compositions formulated for transmucosal delivery of tocotrienols.

Azure said that the application through its wholly-owned subsidiary Invictus Biotechnology Pty Ltd was titled ‘Transmucosal delivery of tocotrienols’ and would provide intellectual property protection until 2040.

The company said that the original technology was described in a previous granted patent and it had developed improvements specifically focused on the improved transmucosal delivery of tocotrienols as the active pharmaceutical ingredient and improvements in the manufacture of these formulations.

Azure said it held granted patents in major markets including the US, Europe, the UK, Japan, China and Australia.

Azure is a public unlisted company.

ATOMO DIAGNOSTICS

Atomo says the Sydney-based Prep Health Pty Ltd will distribute its HIV Self-test through its on-line subscription service in Australia.

Atomo managing-director John Kelly told Biotech Daily that Prep Health was a subsidiary of an unnamed major health company.

The company said that Prep Health would have the exclusive supply of the Atomo HIV Self-Test to Prep users in Australia through its on-line subscription service.

Atomo said that pre-exposure prophylaxis (Prep) was a daily course of anti-retroviral drugs taken by at risk people to protect themselves from HIV infection and was “known to be extremely effective at preventing HIV when taken with high adherence daily or on-demand”.

The company said that the use of Prep required regular HIV testing to ensure efficacy.

Atomo said that Prep Health had committed to buy not less than 10,000 HIV tests from Atomo during 2021 for use in Australia and the companies “expressed interest in expanding this arrangement to international markets, with commercial discussions ongoing”.

The company said that an independent study by the Johannesburg, South Africa-based Wits Reproductive Health and HIV Institute assessed the test for usability and performance in the hands of untrained users.

Atomo said the test was “well-performed by lay users, with 100 percent of participants reporting that it was easy to use”.

The company said that the findings of the study were likely to support the commercial rollout of the HIV self-tests.

Atomo said that since July 2020, Atomo HIV self-test products had been supplied to Australia, Germany, UK, Vietnam, Taiwan, South Africa and multiple countries throughout Africa, with product registrations in process in other countries in Africa, Asia and South and Central America.

Atomo fell half a cent or 1.6 percent to 31.5 cents with one million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says it has appointed Melbourne's Grapeworks Pty Ltd as its Australian distributor of its Sentia wine sulphur dioxide analyzer.

Universal Biosensors said the agreement was for an initial five year-term and Grapeworks had placed its first order for \$300,000 in testing systems.

The company has previously developed and commercialized the Onetouch Verio blood glucose test for Johnson & Johnson and the Xprecia Stride coagulation analyzer for Siemens Healthcare (BD: Feb 21, 2011; Dec 9, 2014; Oct 5, 2016).

Today, Universal Biosensors chief executive officer John Sharman said the Sentia launch was the company's "first new product in almost seven years".

"We believe Sentia has the potential to change the way wine testing is performed globally," Mr Sharman said.

He said that Grapeworks sold a range of production equipment, winemaking, cider and brewing consumables and supplies.

Grapeworks managing-director Malcom Wilson said "the future testing capability for glucose, fructose, and malic acid will add significant value to the winemaking industry".

Universal Biosensors fell 2.5 cents or 5.1 percent to 46.5 cents.

EMVISION

Emvision says that 16,789,351 shares, 5,000,000 options and 6,000,000 performance rights will be released from ASX escrow on December 13, 2020.

Emvision said it the options would be exercisable at 35 cents by December 31, 2021.

The company said a further 1,400,000 options exercisable at 35 cents by December 31, 2021 would be released from voluntary escrow.

According to Emvision's most recent Appendix 2A application for quotation of securities announcement, following the release of the shares from ASX escrow, it would have 70,212,860 shares available for trading.

Emvision fell 11 cents or 3.2 percent to \$3.34.

COGSTATE

Cogstate says it has appointed Darren Watson as chief financial officer from February 1, 2021 and Ben Bloomfield as chief technology officer from January 11, 2021.

Cogstate said Mr Watson had more than 20 years working in the technology sector including with IBM Australia and New Zealand, China and Singapore.

The company said that Mr Watson held a Bachelor of Business from Victoria's Bendigo College of Advanced Education.

Cogstate said Mr Bloomfield worked for 15 years in management and information technology consulting, including with Accenture, IBM Global Business Services and Capgemini and was previously gambling company Tabcorp's head of technology, wagering and media and the former chief executive officer at News Limited company Punters.com.au.

Cogstate said Mr Bloomfield held a Bachelor of Business from the University of Sydney.

Cogstate was up 6.5 cents or 6.5 percent to \$1.07.