

Biotech Daily

Thursday October 31, 2019

Daily news on ASX-listed biotechnology companies

- * ASX DOWN, BIOTECH UP: ANTISENSE UP 11%; KAZIA DOWN 7.5%
- * AUSBIOTECH INVEST, PARTNERING; CONFERENCE GONGS
- * VICTORIA AAMRI WANTS \$20m PA FOR RESEARCH 'INDIRECT COSTS'
- * NEUREN: ACADIA STARTS PHASE III TROFINETIDE RETT TRIAL
- * STARPHARMA: 'DEP-GEMCITABINE BEST FOR PANCREATIC CANCER IN MICE'
- * INVION, PETER MACCALLUM ANO-GENITAL CANCER STUDIES
- * PHYLOGICA 'UNDERWRITTEN' RIGHTS OFFER TO RAISE \$26.8m
- * EMVISION ASSEMBLES 1st PORTABLE BRAIN SCANNER FOR STROKE TRIAL
- * TOTAL BRAIN, VAULT PARTNER FOR MENTAL HEALTH PLATFORM
- * MGC PRESCRIBES 1,000 MARIJUANA DOSES
- * DR MUCHNICKI, MJGD, JGM TAKE 5% OF GENETIC TECHNOLOGIES
- * PETER RUBINSTEIN, IRWIN, RIP TAKE 6% OF GENETIC TECHNOLOGIES
- * NANOSONICS APPOINTS DR LISA MCINTYRE DIRECTOR
- * CELLMID APPOINTS BRIAN MCGEE U.S. ADVANGEN CEO

MARKET REPORT

The Australian stock market fell 0.39 percent on Thursday October 31, 2019, with the ASX200 down 26.1 points to 6,663.4 points. Twenty of the Biotech Daily Top 40 stocks were up, 12 fell and eight traded unchanged. All three Big Caps were up.

Antisense was the best, up one cent or 11.1 percent to 10 cents with 1.7 million shares traded. Orthocell climbed 9.3 percent; LBT was up 7.9 percent; Imugene improved 6.8 percent; Oncosil and Opthea were up five percent or more; Dimerix, Resonance, Uscom and Volpara were up more than four percent; Nanosonics was up 3.2 percent; Compumedics, Optiscan, Pharmaxis, Polynovo and Universal Biosensors rose more than two percent; Prescient and Telix were up more than one percent; with Cochlear, CSL, Medical Developments, Neuren and Resmed up by less than one percent.

Kazia led the falls, down 3.5 cents or 7.5 percent to 43 cents, with 96,241 shares traded. Patrys, Pro Medicus and Proteomics fell five percent or more; Avita, Cyclopharm, Genetic Signatures, Impedimed and Next Science lost more than three percent; Clinuvel and Osprey shed more than two percent; with Paradigm down 0.3 percent.

AUSBIOTECH

Ausbiotech says that 25 companies presented to more than 350 investors at its Australia Biotech Invest and Partnering 2019 session, today.

Ausbiotech said the one day showcase of companies to investors, as part of the three-day Melbourne conference, featured four keynote speakers addressing the venture capital, large pharmaceutical company investments and valuations of prospective investments. The industry organization said that each company had eight minutes to present their technology and case for investment.

Ausbiotech, Johnson & Johnson Innovation Awards

Ausbiotech said that the inaugural Ausbiotech and Johnson & Johnson Innovation Industry Life Sciences Legacy Award was won by US philanthropist Chuck Feeney. According to his Atlantic Philanthropies website, Mr Feeney had invested \$US8 billion (\$A11.6 billion) around the world and between 1998 and 2016, invested \$US368 million (\$A531.5 million) in Australia for medical research.

Former Queensland Premier Peter Beattie said the Smart State partnership with Chuck Feeney "reshaped biotechnology research in Queensland".

"The legacy of his investments left world class research institutions producing outcomes which are savings lives," Mr Beattie said.

Former Victoria Premier and Treasurer John Bumby said that Mr Feeney was "a believer in the power of medical research and life sciences to change lives for the better".

"His contribution to the sector in Victoria has been immense and transformational [and] we are all indebted to Chuck for his great sense of optimism, his generosity and his vision," Mr Brumby said

Queensland Premier Annastacia Palaszczuk said Atlantic Philanthropies had invested about \$300 million in the state, supporting the Brain Institute, the Berghofer Institute, the Institute for Health and Biomedical Innovation and the Translational Research Institute. Ausbiotech said the Leadership Award was won by MTP Connect chair Sue MacLeman who was "honored for decades of leadership in the Australian life sciences and medical technologies sector".

Ms MacLeman was formerly Benitec and MTP Connect chief executive officer and currently held directorships with Palla Pharma, Oventus, the Victorian Government agency Veski and was chair of Anatara, Novita and MTP Connect.

Ausbiotech said Polynovo won the Company of the Year award and under chief executive officer Paul Brennan had commercialized its Novosorb bio-resorbable wound treatment. The industry organization said that in five years, the company had gone from a staff of five and a market cap of \$30 million to a 60-staff operation with an accredited cleanroom facility, a market capitalization of \$1.4 billion and "secured its place in [the] ASX 200". Ausbiotech said that Oncores Medical was awarded Emerging Company of the Year. The organization said that Oncores was led by chief executive officer Dr Kath Giles, with technology from the University of Western Australia, the Harry Perkins Institute and was developing a hand-held device to monitor the margin of tumors during breast conservation surgery to help surgeons delineate cancerous tissue.

Ausbiotech said the aim of the technology was to reduce the amount of follow-up surgery required by women with breast cancer.

Ausbiotech chief executive officer Lorraine Chiroiu said the Awards were "a celebration of the innovation excellence happening across the country and demonstrate what can be achieved when leadership, passion, technical expertise, and business acumen unite". Johnson & Johnson Innovation executive Kathy Connell said the awards "recognize the important and noble work that's occurring in Australian biotechnology to advance biomedical research and healthcare innovation for people all around the world".

ASSOCIATION OF AUSTRALIAN MEDICAL RESEARCH INSTITUTES

The Victorian chapter of the Association of Australian Medical Research Institutes wants the Victoria Government to spend a further \$20 million on "indirect costs".

Vic-AAMRI said the \$20 million a year was needed "to cover the gaps in research grants". Vic-AAMRI said it had "identified the key issues facing the sector and has put forward a submission to the Victorian Government for consideration in the next State budget".

The industry association said that research grants covered the salaries of researchers, the supplies for the research and some equipment, but "anything else needed in the day of a life of a researcher at an independent medical research institute, is not".

Vic-AAMRI said the additional costs included water, electricity, the cost of filing a patent, payroll, the commercialization team that makes the deal with the company who helps run the clinical trial were indirect costs.

The organization said that the Victoria Government provided funding for these costs through the Operational Infrastructure Support Program, but "institutes currently face a funding gap for indirect costs of over \$100 million a year".

Vic-AAMRI chair Prof Brendan Crabb said that indirect costs were "an ongoing complex problem that every institute is continually trying to solve".

"Last year the indirect costs of research for Victoria's independent medical research institutes totalled \$175 million dollars, of which \$34 million was covered by the Victorian Government indirect costs program," Prof Crabb said.

"This year we're asking for an extra \$20 million a year from the Victorian Government for the indirect costs program, to help our researchers focus on what they do best and remove some of that burden from the institutes," Prof Crabb said.

According to the current Google Maps, apart for the Peter MacCallum Cancer Centre, none of the research buildings in the Parkville Precinct have solar panels to offset the cost of electricity.

NEUREN PHARMACEUTICALS

Neuren says its North American licencee Acadia Pharmaceuticals has begun its 180patient, phase III, 'Lavender' trial of trofinetide for Rett syndrome.

Previously, Neuren said Acadia would pay \$630 million in upfront fees, milestones and royalties for North American rights to trofinetide and, this year, said it would begin a phase III trial of trofinetide for Rett syndrome by July 2019 (BD: Aug 7, 2018, Feb 4, 2019). Today, the company said the study would be a 12-week, placebo-controlled, double-blind,

randomized trial of 180 girls and young women, aged five to 20 years, with Rett syndrome. Neuren said the primary endpoints of the study were symptom improvement using the caregiver Rett Syndrome Behaviour Questionnaire (RSBQ) and the clinician Clinical Global Impression Scale-Improvement (CGI-I).

The company said that Acadia's 'Lilac' trial would be a nine-month extension trial to evaluate long-term tolerability, safety and efficacy of trofinetide.

Neuren said development and trial costs would be fully funded by Acadia and it would have free and full access to all data to commercialize outside North America.

Neuren executive chairman Dr Richard Treagus said the start of the phase III trial was "a very important milestone for all stakeholders as we work towards achieving an approved treatment for patients and families living with the debilitating effects of Rett syndrome". "With our lead drug trofinetide now in phase III and our second drug NNZ-2591 moving into clinical trials for three separate orphan drug designated childhood disorders in 2020, Neuren is in a fundamentally strong position with a diverse and valuable pipeline," he said. Neuren was up one cent or 0.4 percent to \$2.29.

STARPHARMA HOLDINGS

Starpharma says its dendrimer enhanced product (DEP) gemcitabine outperforms gemcitabine alone or in combination Abraxane for pancreatic cancer in mice.

Starpharma said that gemcitabine alone or in combination with other therapies such as Abraxane (paclitaxel) for pancreatic cancer.

The company said the study used a human pancreatic cancer xenograft mouse model to assess efficacy, inoculating mice sub-cutaneously with human pancreatic cancer cells and dosing the mice with saline, DEP-gemcitabine, standard gemcitabine or gemcitabine with Abraxane on days one, 10 and 18.

The company said it measured tumor size twice weekly and analyzed tumor growth inhibition data.

Starpharma said it found that mice treated with DEP-gemcitabine had mean tumor volumes that were "significantly improved" compared to those treated with standard gemcitabine (p < 0.0001).

The company said DEP-gemcitabine with Abraxane "significantly outperformed" a combination of standard gemcitabine and Abraxane (p < 0.005).

Starpharma said that it had filed a patent covering DEP-gemcitabine, which if granted would provide intellectual property protection until 2040.

Starpharma said that pancreatic cancer was a leading cause of cancer death, with a 5-year survival rate of seven percent.

The company said that gemcitabine and Abraxane had "significant bone marrow toxicities [and] an important attribute of DEP products [was] a lack of bone marrow toxicities in both pre-clinical and clinical studies".

Starpharma was unchanged at \$1.16.

INVION

Invion says the Peter MacCallum Cancer Centre will undertake pre-clinical studies of its photodynamic therapy for ano-genital cancers including penile and anal cancer.

Last year, Invion said pre-clinical data from studies with Melbourne's Hudson Institute of Medical Research for its Photosoft photodynamic therapy found that it killed ovarian cancer cells in-vitro (BD: Jul 5, 2018).

Today, the company said the Peter MacCallum Cancer Centre pre-clinical studies would aim to identify the molecular mechanisms of squamous cell cancer deaths induced by IVX-PDT, developed from the Photosoft technology.

Invion said the research would determine IVX-PDT efficacy for squamous cell cancer tumor regression and induced cell destruction for ano-genital cancers.

The company said the studies would determine the impact of IVX PDT on immune function in-vivo, would establish the efficacy of IVX PDT for the ablation of squamous cell cancers in-vivo and assess effective dose treatments for patients.

Invion said the studies would begin next year and would be led by Cancer Centre head gastro-intestinal cancer Prof Robert Ramsey.

"We are keen to investigate the potential use of IVX-PDT in ano-genital cancers where new treatments are badly needed," Prof Ramsey said.

"Peter Mac has the world's largest bank of annotated squamous cell cancer lines from patients with anal and penile cancers," Prof Ramsey said.

Invion chief executive officer Craig Newton said that "for ano-genital cancer, IVX-PDT may offer a potential treatment option based on access to the tumor by the activating light and a different mode of tumor cell killing".

Invion was unchanged at 1.3 cents with 7.2 million shares.

PHYLOGICA

Phylogica says it expects to raise up to \$26.8 million in a "fully underwritten" one-for-five, non-renounceable entitlement offer at 5.5 cents a share.

Phylogica said the price was an 11 percent discount to the October 30, 2019 closing date and a 16 percent discount to the 14-day volume weighted average price to October 30.

The company said the record date would be November 4, 2019, with the institutional entitlement offer to close on November 4 and the retail entitlement offer to open on November 7 and close on November 18.

Phylogica said the offer would be fully underwritten by Australian Land, controlled by non-executive chairman Alan Tribe.

The company said the funds would be used to develop its lead drug molecule, including formal preclinical investigational new drug enabling studies, for clinical developing costs, development work for additional programs, to cover the offer costs and for working capital. Phylogica was in a trading halt at 6.2 cents.

EMVISION MEDICAL DEVICES

Emvision says it has assembled the first portable brain scanner for its stroke clinical trial and is calibrating it for Brisbane's Princess Alexandra Hospital.

Last month, Emvision said it would begin a pilot trial of its non-invasive, low-cost portable brain scanner for stroke at the hospital (BD: Sep 3, 2019).

Today, the company said a further two units would be completed, calibrated and verified and four complete part sets would be fabricated in the next four weeks.

Emvision chief executive officer Dr Ron Weinberger said he was "thrilled to complete our first clinical unit build and to deliver it to the Princess Alexandra Hospital shortly".

"The Emvision device represents a breakthrough opportunity for imaging the brain, at the point-of-care, in a manner otherwise not possible today," Dr Weinberger said.

"Our [intensive care unit] and neurology clinical collaborators are very excited to start the trial as soon as possible," Dr Weinberger said.

Emvision was unchanged at 85 cents.

TOTAL BRAIN

Total Brain says it will collaborate with Melbourne's Vault Intelligence Partners to integrate its mental health platform with Vault's Solo product to lift performance.

Total Brain said it would use the Solo product to identify and manage risk through the mental health fitness assessment and screening functionality of its platform.

The company said Vault would access its library of brain and mind training exercises.

Total Brain was up 0.3 cents or 5.9 percent to 5.4 cents.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says it has passed 1,000 prescriptions for its 5.0 percent tetrahydrocannabinol Cannepil and 100 percent cannabidiol MXP100 products in Australia and the UK. Earlier this month, MGC said it had passed 400 prescriptions, an increase of 200 percent for the two weeks to September 30, 2019 (BD: Oct 3, 2019).

Today, the company said the number of units more than doubled, was ahead of schedule and an average of 25 units were prescribed every business day in October, increasing 20 percent over the last two weeks.

MGC was up 0.1 cents or three percent to 3.4 cents with 2.8 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies executive chairman Dr Jerzy Muchnicki, MJGD Nominees and JGM Investment say they have become substantial with 221,352,553 shares or 5.45 percent. The Melbourne-based Dr Muchnicki, MJGD and JGM said that on October 28, 2019 they acquired 200,849,309 shares at 0.4 cents a share.

Last week, Genetic Technologies said it had raised \$4.5 million in an underwritten one-fortwo rights offer at 0.4 cents a share, with shareholders applying for \$786,000 in shares (BD: Oct 25, 2019).

Genetic Technologies was up 0.1 cents or 25 percent to 0.5 cents with 1.7 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies director Peter Irwin Rubinstein, Irwin Biotech Nominees and RIP Opportunities say they have become substantial with 248,132,009 shares or 6.11 percent. The Melbourne-based Mr Rubinstein, Irwin Biotech and RIP said that on October 28, 2019 they acquired 200,849,309 shares at 0.4 cents a share. Genetic Technologies

NANOSONICS

Nanosonics says it has appointed Dr Lisa McIntyre as a non-executive director effective from December 13, 2019.

Nanosonics said Dr McIntyre had 20 years' experience as a senior partner for Boston and London-based LEK Consulting, where she led its US biotechnology practice.

The company said Dr McIntyre was currently a non-executive director for Icare New South Wales, HCF Group and the University of Sydney and an advisor for the New South Wales Generations Fund, the Australian Institute of Company Directors' Corporate Governance Committee and for Studiosity.

Nanosonics said Dr McIntyre held a Bachelor of Science from the University of Sydney and a Doctor of Philosophy from England's University of Cambridge.

Nanosonics was up 21 cents or 3.2 percent to \$6.80 with 1.7 million shares traded.

CELLMID

Cellmid says it has appointed Brian McGee as chief executive officer of its US subsidiary Advangen LLC effective from tomorrow.

Cellmid said Mr McGee had 30 years' experience in sales, marketing and operations in the beauty and hair care industry.

The company said Mr McGee had worked as a consultant for its Évolis brand since May 2019.

Cellmid fell half a cent or 2.4 percent to 20.5 cents.