Biotech Daily

Thursday November 19, 2020

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: UNIVERSAL BIO UP 11.5%; ALTERITY DOWN 14%**

*** IMMUTEP RAISES $30m, EXPANDS TACTI-002 TRIAL, HNSCC TRIAL**

*** QUEENSLAND UNI: PRANA'S PBT2 'KILLS RESISTANT BACTERIA' IN MICE**

*** PRO MEDICUS, ZWANGER PESIRI $8.5m VISAGE-7 DEAL**

*** POLYNOVO NOVOSORB IN BENELUX, SWEDEN**

*** TELIX $885k BELGIUM GRANT FOR PROSTATE CANCER IMAGING**

*** NEUREN FINAL NNZ-2591 TRIAL APPROVAL**

*** CANADA APPROVES PAINCHEK PAIN ASSESSMENT**

*** MICRO-X, CARESTREAM NANO DISTRIBUTION 'NON-EXCLUSIVE'**

*** STARPHARMA SPL7013 NASAL SPRAY 'ACTIVE AGAINST RSV' IN-VITRO**

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*** PLATINUM INVESTMENTS TAKES 6% OF ANTISENSE**

*** MEDADVISOR DIRECTOR JIM XENOS, KOJENT DILUTED TO 6%**

*** PERENNIAL TAKES 5% OF MEDADVISOR**

*** MEDADVISOR DIRECTOR JOSH SWINNERTON, WAVEY BELOW 5%**

*** DAVID SIETSMA REDUCES TO 9% IN PYC**

MARKET REPORT

The Australian stock market was up 0.25 percent on Thursday November 19, 2020, with the ASX200 up 16.1 points to 6,547.2 points. Sixteen of the Biotech Daily Top 40 stocks were up, 20 fell, three traded unchanged and one was untraded. All three Big Caps fell.

Universal Biosensors was the best, up 4.5 cents or 11.5 percent to 43.5 cents, with 1.2 million shares traded. Kazia climbed 11.15 percent; Next Science and Osprey improved more than four percent; Compumedics, Neuren, Polynovo and Uscom were up more than three percent; Avita, Cyclopharm and Opthea rose more than two percent; Paradigm, Starpharma and Telix were up one percent or more; with Mesoblast and Nanosonics up by less than one percent.

Alterity led the falls on apparently immaterial good news not posted to the ASX, down 0.6 cents or 14.3 percent to 3.6 cents, with 53.4 million shares traded. Amplia and Patrys lost more than nine percent; Immutep and Imugene were down more than six percent; Medical Developments shed 5.2 percent; Actinogen, Antisense, Cynata and Impedimed fell more than four percent; LBT lost 3.85 percent; Cochlear, Oncosil, Optiscan, Resonance and Volpara shed two percent or more; Clinuvel, Genetic Signatures, Prescient, Pro Medicus, Proteomics and Resmed were down more than one percent; with CSL down 0.7 percent.

IMMUTEP

Immutep says it has raised $29.6 million in a placement at 24 cents a share and will expand its Tacti-002 trial of IMP321, or eftilagimod alpha, with Keytruda for cancers.
Immutep said Australian Ethical Investment, Perennial Value Management, Regal Funds Management, Firetrail Investments and Ridgeback Capital invested in the placement.
The company said it would use the funds for its immuno-oncology and auto-immune disease clinical program, including IMP321 as well as the cell-line development of IMP761, research and development, manufacturing, and general working capital.
Immutep said the 24 cents issue price was an 11.2 percent discount to the 30-day volume-weighted average price, with Bell Potter the lead manager and bookrunner and Taylor Collison as co-manager.
Separately, Immutep said it would expand its phase II Tacti-002 trial to up-to 183 patients.
The company said the two-stage, non-comparative, open-label, single-arm, multi-centre clinical study trial was a collaboration with the Kenilworth, New Jersey Merck & Co and enrolled first or second line non-small cell lung cancer (NSCLC) and second line head and neck squamous cell carcinoma patients.
Immutep said 74 additional patients would be enrolled into part A of the trial, which recruited first line NSCLC patients, with the first patient expected to be enrolled this year.
Immutep chief executive officer Marc Voigt said the interim results reported from first line NSCLC patients were “consistently encouraging and signal good efficacy, particularly for low [programmed death-ligand 1] expressing patients who do not typically respond to immune checkpoint therapy”.
“Not only does this give us great confidence expanding the Tacti-002 trial, but it also validates our strategy to form and grow multiple collaborations with innovative large pharma companies, such as [Merck], that are seeking to augment the efficacy of their existing approved products, like Keytruda,” Mr Voigt said.
Immutep said it had plans for an additional phase II trial of IMP321 in first line head and neck squamous cell carcinoma, based on the Tacti-002 trial results.
Immutep fell two cents or 6.8 percent to 27.5 cents with seven million shares traded.

UNIVERSITY OF QUEENSLAND
ALTERITY THERAPEUTICS (FORMERLY PRANA BIOTECHNOLOGY)

The University of Queensland says Alterity's PBT2 has proven "effective at treating some of the most persistent, life-threatening antibiotic-resistant bacteria" in mice.

The then Prana was developing PBT2 as a treatment for Alzheimer's disease, with promising phase IIa efficacy data published in 2008, but in 2014 the company reported that its imaging trial of PBT2 for Alzheimer's disease did not meet its primary endpoint of reducing amyloid beta plaques (BD: Jul 30, 2008; Apr 1, 2014)

In 2011, the company attempted to re-purpose the drug for Huntington's disease, but after the ASX closed for Christmas in 2016, the company disclosed that European regulators wanted more pre-clinical work before allowing a phase III trial of PBT for Huntington's disease (BD: Apr 20, 2011; Dec 23, 2016).

Today, the University of Queensland said that with the University of Melbourne and Queensland's Griffith University PBT2 had been shown to be "effective at disrupting and killing … Gram-negative bacteria that [caused] infections such as pneumonia, bloodstream infections and meningitis".

The research article, titled 'Repurposing a neurodegenerative disease drug to treat Gram-negative antibiotic-resistant bacterial sepsis' was published in the journal Science Translational Medicine and an abstract is available at: https://stm.sciencemag.org/content/12/570/eabb3791.

The University's Prof Mark Walker said the metal transport drug might offer a last line of defence against difficult-to-treat superbugs.

"The emergence of antibiotic-resistant superbugs is an urgent threat to human health, undermining the capacity to treat patients with serious infection," Prof Walker said.

"Alternative strategies to treat such multi-drug resistant bacteria are urgently needed."

"Our team hypothesized that by using this experimental Alzheimer's treatment to disrupt the metals inside these bacteria, we would also disrupt their mechanisms of antibiotic resistance," Prof Walker said.

Prof Walker told Biotech Daily that the researchers had found that zinc and iron were implicated in antibiotic resistant bacteria and a search of the literature located PBT2 as a compound able to disrupt the metals.

"This was shown to be the case, with the Alzheimer's drug – combined with the antibiotic polymyxin – successfully tackling antibiotic-resistant superbugs like Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa and Escherichia coli," Prof Walker said in the University media release.

Griffith University's Prof Mark von Itzstein said the treatment was effective and offered a range of other benefits.

"Based on its use as an experimental Alzheimer's treatment, there's been a significant amount of solid science done on this drug already," Prof von Itzstein said. "We know, for example, that clinical studies of PBT2 show that it is safe for use in humans."

"And, given that we've been able to combine it with the antibiotic polymyxin to treat polymyxin-resistant bacteria, we may be able to make other now-ineffective antibiotics become effective again for treating infectious diseases," Prof von Itzstein said.

"This could resharpen, so to speak, some of the weapons we thought we'd lost in our fight against antibiotic-resistant bacteria," Prof von Itzstein said.

The University of Melbourne's Prof Christopher McDevitt said that mouse studies had shown that "the combination of polymyxin and PBT2 killed polymyxin-resistant bacteria, completely clearing any infection".

The University of Queensland and Alterity declined to comment on commercial terms.

Alterity fell 0.6 cents or 14.3 percent to 3.6 cents with 53.4 million shares traded.

PRO MEDICUS

Pro Medicus says it has an $8.5 million, five-year agreement with the Long Island-New York outpatient radiology provider Zwanger Pesiri for its Visage-7 imaging technology.
Pro Medicus said the Visage-7 technology would be implemented across all Zwanger Pesiri locations in the US and the company was “one of the largest private outpatient radiology providers in the US”.
Zwanger Pesiri chief executive officer Dr Steve Mendelsohn said that since implementing Visage-7 five years ago “we have experienced significant increases in radiologist productivity and clinical accuracy which has underpinned our substantial growth over that time”.
Pro Medicus chief executive officer Dr Sam Hupert said the company believed that the Visage-7 technology provided “the best return on investment of any system in the market from both financial and clinical perspectives”.
Pro Medicus fell 33 cents or one percent to $31.85 with 384,060 shares traded.

POLYNOVO

Polynovo says it has extended its Novosorb distribution agreement with Polymedics Innovations to include Belgium, the Netherlands, Luxembourg (BeNeLux) and Sweden.
In 2019, Polynovo said it had appointed the Stuttgart, Germany-based Polymedics to distribute its Novosorb biodegradable temporizing matrix wound treatment in Germany, Austria, and Switzerland (BD: Apr 29, 2019).
Polynovo was up nine cents or 3.1 percent to $3.03 with 4.05 million shares traded.

TELIX PHARMACEUTICALS

Telix says it has received EUR545,000 ($A885,452) from the Walloon, Belgium regional government for research and development of TLX591-CDx for prostate cancer imaging.
Telix said the grant, to its subsidiary, Advanced Nuclear Medicine Ingredients SA, was part of a EUR1,320,000 ($A2,144,580) grant to support the pre-clinical research and development and early clinical development of TLX591-CDx.
The company said it was required to repay 30 percent of the loan over 10 years if the funds resulted in commercialized products or intellection property.
Telix was up three cents or 1.1 percent to $2.83 with 793,191 shares traded.

NEUREN PHARMACEUTICALS

Neuren says it has ethics approval for the final stage of its phase I trial of NNZ-2591 for Phelan-McDermid, Angelman and Pitt Hopkins syndromes.
In May, Neuren said it had begun its first phase I, 30-patient clinical trial of NNZ-2591 in healthy Australian adults to assess safety, tolerability and pharmacokinetics, following orphan drug designation by the US Food and Drug Administration for all three syndromes (BD: Oct 11, 16, 2019; May 7, 2020).
Today, the company said the final stage of the double-blind, placebo-controlled, phase I trial would dose 16 subjects in two dosing cohorts, twice daily for seven days and measure adverse events, physical and laboratory measurements and pharmacokinetics.
Neuren said it expected to complete the phase I trial in January 2021 and the results would be used for its application to the US Food and Drug Administration for a phase II trial of NNZ-2791 in children with neuro-developmental disorders.
Neuren was up 4.5 cents or 3.5 percent to $1.335.

PAINCHEK

Painchek says Health Canada has approved its smartphone application pain assessment and monitoring software for distribution in Canada.

Last month, Painchek said it had extended its partnership with the Montreal-based Alayacare to sell its pain assessment tool in Canada would begin sales following regulatory approval (BD: Oct 28, 2020).

Today, the company said it had access to Canada's $5 billion market for in-home care and support services and expected to begin sales by April 2021.

Painchek chief executive officer Philip Daffas said the company was "really pleased to have secured this approval from Health Canada, as it allows us to grow into the sizeable Canadian market with the help of our partner Alayacare, but also move into aged care services and hospitals in Canada".

Painchek fell 0.2 cents or 2.2 percent to nine cents with 5.7 million shares traded.

MICRO-X

Micro-X says its agreement with Carestream Healthcare for the distribution of its DRX Revolution Nano mobile medical x-ray device has become non-exclusive.

Micro-X said it signed the-then exclusive distribution deal with the Rochester, New York-based Carestream on July 25, 2016, but due to the Covid-19 pandemic there has been a recent "surge" in Nano orders which required Micro-X to increase production capacity and reduce delivery times to meet demand.

The company said it planned to "develop additional paths to market for its bedside imaging x-ray units, either selling directly or via distributors and agents".

Micro-X said Carestream would continue to sell and support the Carestream-branded DRX Revolution Nano in all markets.

The company said it was required to maintain appropriate levels of spare parts for Carestream and its customers.

Micro-X was up 4.5 cents or 15.25 percent to 34 cents with 3.3 million shares traded.

STARPHARMA

Starpharma says its Viraleze SPL7013 anti-viral nasal spray "has potent antiviral activity against respiratory syncytial virus" in-vitro.

In August, Starpharma said it had reformulated SPL7013, the active ingredient in its Vivagel for bacterial vaginosis and condom coatings, into anti-viral nasal sprays to inhibit severe acute respiratory-coronavirus-2 (Sars-Cov-2), the virus that caused Covid-19, and testing confirmed SPL7013 made Sars-Cov-2 inactive (BD: Aug 25, 2020).

Today, the company said respiratory syncytial virus (RSV) was a common and highly contagious virus that affected the lungs and airways.

Starpharma said its SPL7013 compound "was effective against RSV when used either before or after exposure of cells to the virus, indicating that the nasal spray would be effective if used before or after exposure to the virus".

Starpharma chief executive officer Dr Jackie Fairley said that "what these results confirm, is that SPL7013 has broad spectrum antiviral activity, and that Viraleze could play an important role for future pandemic preparedness".

"The rapid development and commercialization of SPL7013 as Viraleze anti-viral nasal spray is on track, with the product set to be available in some markets [by July 2021]," Dr Fairley said.

Starpharma was up 2.5 cents or 1.9 percent to $1.34 with 1.2 million shares traded.

BIONOMICS

Bionomics says Adelaide's Carina Biotech will licence its oncology drug candidate BNC101 for chimeric antigen receptor T-cell (Car-T) therapy for cancer.

Carina chief executive officer Dr Deborah Rathjen was previously Bionomics chief executive officer and resigned after the company failed to commercialize BNC105 for cancers and BNC210 for anxiety (BD: Aug 3, 2011; Mar 19, 2014; Oct 2, Nov 12, 2018).

In 2013, Bionomics acquired the cancer stem cell drug BNC101 (formerly ET101) with Biogen Idec's San Diego spinout, Eclipse Therapeutics, and said Eclipse had invested significant resources in the program, which was used to identify antibody therapeutics that inhibited the growth of cancer stem cells (BD: Sep 17, 2012; Feb 11, 2013).

Today, Bionomics said that BNC101 was a first-in-class humanized monoclonal antibody to LGR5, which was overexpressed in cancer stem cells in solid tumors including colorectal, breast, pancreatic, ovarian, lung, liver and gastric cancers and had "the potential to guide Car-T therapeutic development".

Carina's website said that chimeric antigen receptor T cell therapy harnessed the body's immune system to fight cancer and Car-T cells were "made from a patient's own T-cells, key cells of the immune system".

"The T-cells are isolated from a sample of the patient's blood and then genetically modified to express a chimeric antigen receptor on their surface … [and] targeted to recognize a specific marker on the surface of cancer cells." Carina said.

Bionomics said that Carina would fund "all research and development activities" and Bionomics was eligible to receive up to $118 million in clinical and development milestones plus royalties if Carina fully developed and marketed the new therapy.

The company said that should Carina sub-licence the Car-T treatment, Bionomics was eligible to share in the sub-licencing revenues in early clinical development "and receive a substantial double-digit portion of the revenues in later stages of clinical development".

Bionomics executive chair Dr Errol De Souza said the company was "very excited to have … this agreement with Carina Biotech given the opportunity Car-T therapy offers".

Dr Souza said Bionomics retained BNC101 for other types of therapies.

Last year, Prescient said it would work with Carina to develop chimeric antigen receptor-T cell combination therapies for cancer by combining its targeted therapies with Carina's cell therapies and it would share any resulting intellectual property (BD: Nov 18, 2019).

In May, Prescient said it would have the exclusive rights to any intellectual property from its research collaboration with Carina (BD: May 11, 2020).

Bionomics was up one cent or 8.3 percent to 13 cents with 3.4 million shares traded.

RESAPP HEALTH

Resapp says it will integrate its Resappdx respiratory diagnostic software into Workplace Medicine Australia's Medetective corporate health platform.

Resapp said it had a two-year agreement with Brisbane's Workplace Medicine Australia (WMA), which provided software programs to workplaces "to raise the standard for workplace health and wellbeing management … and strengthen productivity".

The company said it would receive an undisclosed monthly fee for every worker that WMA's health software covered at a client workplace.

Resapp managing-director Dr Tony Keating said that "as the adoption of telehealth continues in Australia, Resapp is witnessing increased interest in its software".

"This agreement with WMA is very important, as it considerably broadens the company's visibility into new, large sectors with substantial workforces," Dr Keating said.

Resapp was up 0.1 cents or 1.1 percent to 9.1 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says its annual general meeting voted a 35.34 percent first strike against the remuneration report and director Chris Fullerton has resigned.

Paradigm said were 21,993,784 votes (35.34%) opposed to the remuneration report, with 40,233,204 votes (64.66%) in favor, earning a 'first strike,' but all resolutions put to the meeting were passed.

Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and if passed the directors must stand for re-election.

The company said that the resolution to re-elect director Mr Fullerton was withdrawn prior to the meeting, with Mr Fullerton resigning as a director from today.

The company said the resolution to issue interim chair Paul Rennie 600,000 loan shares was opposed by 23,815,272 votes (37.96%) with 38,924,961 votes (62.04%) in favor.

Paradigm said the issue of 500,000 shares to chief medical officer Dr Donna Skerrett was passed by a slightly wider margin, while resolutions to elect Dr Skerrett as a director and the ratify the prior issue of placement shares passed, with more than 11 percent dissent.

Paradigm's most recent Appendix 2A new issue announcement said the company had 228,072,176 shares on issue, meaning the votes against Mr Rennie's shares, amounted to 10.4 percent of the company, sufficient to requisition extraordinary general meetings.

Paradigm was up three cents or one percent to $3.05 with 724,411 shares traded.

EMYRIA (FORMERLY EMERALD CLINICS)

Emyria says it will partner with Mind Medicine Australia to develop a data-driven clinical model for the safe use of psychedelic-assisted therapies for mental health.

Emyria said the partnership with Melbourne's Mind Medicine would develop a national clinical evidence registry to support research into the safety, effectiveness and cost benefits of psychedelic-assisted therapy using its "real-world evidence" data platform.

The company said that the project was pending the Australian Therapeutic Goods Administration re-scheduling the hallucinogenic drug psilocybin and psychoactive drug 3,4-methyl-enedioxy-methamphetamine (MDMA).

Emyria said that it proposed to use MDMA for treatment-resistant post-traumatic stress disorder and psilocybin for treatment-resistant depression.

Emyria managing director Dr Michael Winlo, said the company was "delighted to support Mind Medicine Australia by developing a scalable psychedelic-assisted therapy care model for patients suffering from treatment resistant post-traumatic stress disorder, treatment resistant depression and substance abuse".

"This partnership has the potential to expand the therapeutic options available for our patients with unmet needs while also creating a unique data registry that can accelerate treatment development and registration," Dr Winlo said.

Emyria was unchanged at 7.6 cents.

LITTLE GREEN PHARMA

Little Green says it has exported 2,400 units of its medical marijuana oils worth $600,000 to the Densborn, Germany-based CC Pharma GmbH.

Little Green said shipment was expected to clear customs in Germany "in the next week" and would be batch-tested and released for distribution through CC Pharma.

Little Green was up four cents or 11.4 percent to 39 cents.

NEUROTECH INTERNATIONAL

Neurotech says it has started clinical product development and formulation for a trial in early 2021 of marijuana licenced from Dolce Cann Global for neurological disorders.
In July, Neurotech said it licenced marijuana strains from Dolce and began investigating the strains for autism, epilepsy and attention deficit hyperactivity disorder, and in September began in-vitro trials (BD: Jul 3, 27, Sep 23, 2020).
Today, the company said it would work with the Melbourne-based ACS Laboratories, the Royal Melbourne Institute of Technology and the Victorian College of Pharmacy to develop the best marijuana strain and an optimal delivery system.
Neurotech said the phase I clinical trial would be conducted under the Australian Therapeutic Goods Administration special access scheme.
Neurotech was up 0.1 cents or 3.7 percent to 2.8 cents with 4.8 million shares traded.

IMAGION BIOSYSTEMS

Imagion has requested a trading halt in relation to “the planning and execution of a potential capital raise”.
Trading will resume on November 23, 2020 or on an earlier announcement.
Imagion last traded at 12.5 cents.

INCANNEX HEALTHCARE

Incannex has requested a trading halt in relation to the results of an IHL-675A in-vivo study and its related US Food and Drug Administration regulatory strategy.
Earlier this month, Incannex said an in-vitro study showed that its IHL-675A cannabidiol-hydroxychloroquine out-performed cannabidiol alone by up-to 767 percent for cytokine inhibition 24 hours after drug administration (BD: Nov 5, 2020).
Trading will resume on November 23, 2020 or on an earlier announcement.
Incannex last traded at 11.5 cents.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific has requested a trading halt in relation to the assessment of drug candidates in the treatment of pulmonary fibrosis associated with post-Covid-19 infections.
Trading will resume on November 23, 2020 or on an earlier announcement.
Neuroscientific last traded at 34 cents.

ANTISENSE THERAPEUTICS

Platinum Investment Management says it has become a substantial shareholder in Antisense with 32,751,370 shares or 5.83 percent of the company.
The Sydney-based Platinum said that on November 17, 2020 it bought 9,000,000 shares for $900,000 or 10 cents a share.
Last week, Antisense said it raised $7.3 million through an oversubscribed placement at 10 cents a share (BD: Nov 11, 2020).
Antisense fell half a cent or 4.8 percent to 10 cents with 4.2 million shares traded.

MEDADVISOR

Medadvisor director Jim Xenos and Kojent Pty Ltd say their 12,535,714 share-holding has been diluted from 8.35 percent to 6.04 percent.
The Melbourne-based Mr Xenos and Kojent said that between December 23, 2019 and November 18, 2020 their holding was gradually diluted, with the most significant dilution on November 18 following the relation placement.
Last week, Medadvisor said it has raised $35 million in a placement and institutional rights offer at 38 cents a share, with the retail rights offer expected to raise a further $20 million (BD: Nov 12, 2020).
Medadvisor fell half a cent or 1.3 percent to 37 cents with 1.1 million shares traded.

MEDADVISOR

Sydney's Perennial Value Management says it has become a substantial shareholder in Medadvisor with 13,157,895 shares or 5.31 percent.
Perennial said that on November 17, 2020 it bought the shares for $5,592,105 or 42.5 cents a share.

MEDADVISOR

Medadvisor director Josh Swinnerton and Wavey Industries say they have increased their holding but been diluted below five percent in the company.
The Melbourne-based Mr Swinnerton and Wavey said that between April 28 and November 18, 2020 their holding was diluted from 15,008,943 shares 6.10 percent to below five percent, through the issue of new shares (see above).
Mr Swinnerton said that on November 18, 2020 he bought 526,316 shares for $200,000 or 38 cents a share.
Biotech Daily calculates that Mr Swinnerton and Wavey hold 4.33 percent.

PYC THERAPEUTICS (FORMERLY PHYLOGICA)

Melbourne's David Sietsma says he has reduced his substantial shareholding in PYC from 291,950,000 shares (9.97%) to 283,996,241 shares (8.96%).
The substantial shareholder notice the 283,996,241 shares had been diluted but did not provide a date or value of the disposal of the 7,953,759 shares as required under the Corporations Act.
Last week, PYC said it had raised $5.4 million in a retail rights offer at 17 cents, taking the total raised to $40.6 million (BD: Nov 13, 2020).
PYC was up half a cent or three percent to 17 cents with 4.1 million shares traded.