Biotech Daily

Wednesday November 3, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PARADIGM UP 23%; OSPREY DOWN 9%**

*** FDA CLEARS PARADIGM PHASE III PPS FOR KNEE OA TRIAL**

*** MTP CONNECT $450k BACKS $1m FOR 5 WA COMPANIES**

*** MEDLAB: DISER APPROVES $27m OFFSHORE RDTI**

*** CORRECTION: BARD1 AGM**

*** MEMPHASYS COMPLETES FELIX VALIDATION, VERIFICATION**

*** LUMOS: CANADA SARS-COV-2 RAPID TEST INTERIM APPROVAL**

*** BCAL: SAMPLE TESTING 'POSITIVE RESULTS', TRIAL BEGINS**

*** NUHEARA FEDERAL HEARING SERVICES PROVIDER**

*** USCOM SPIROSONIC KONESKA TECHNICAL AGREEMENT**

*** ARGENICA: ARG-007 REDUCES HIE BRAIN DEATH 50%, IN RATS**

*** RACE, NEWCASTLE UNI ZANTRENE CANCER DIAGNOSTIC**

*** ZELIRA MARIJUANA TECHNOLOGY; $1.35m UPFRONT DRCN DEAL**

*** MGC BUILDS MALTA CIMETRA FACTORY, $4.8m GRANT**

*** VANGUARD (JUST) BELOW 5% IN COCHLEAR**

MARKET REPORT

The Australian stock market was up 0.93 percent on Wednesday November 3, 2021, with the ASX200 up 68.4 points to 7,392.7 points. Twenty of the Biotech Daily Top 40 stocks were up, 12 fell, seven traded unchanged and one was untraded. All three Big Caps rose.

Paradigm was the best, up 47 cents or 22.8 percent to $2.53, with 8.1 million shares traded. Optiscan climbed 7.3 percent; Actinogen and Imugene were up more than six percent; Kazia and Universal Biosensors rose more than five percent; Cyclopharm, Proteomics and Starpharma improved more than four percent; Mesoblast and Prescient were up more than three percent; Clinuvel, Impedimed and Nanosonics rose two percent or more; Immutep, Pro Medicus and Resmed were up more than one percent; with Cochlear, CSL, Medical Developments, Patrys, Polynovo and Telix up by less than one percent.

Osprey led the falls, down eight cents or 8.9 percent to 82 cents with 13,523 shares traded. Antisense, Next Science, Resonance and Volpara fell four percent or more; Orthocell and Neuren lost three percent or more; Genetic Signatures and Oncosil shed more than two percent or more; with Avita, Compumedics and Opthea down by more than one percent.

PARADIGM BIOPHARMACEUTICALS

Paradigm says the US Food and Drug Administration has cleared its application for a 930-patient, phase III trial of pentosan polysulfate sodium for knee osteoarthritis pain.

In March, Paradigm said it has filed its investigational new drug submission for the randomized, phase III trial of pentosan polysulfate sodium (PPS), marketed as Zilosul, for knee osteoarthritis (BD: Mar 26, 2021).

In May, the company said the FDA had six questions "principally in relation to recently completed non-clinical studies" and in August said that the one remaining question was "directed at the non-clinical interpretation and clinical mitigation relating to one of its recent non-clinical toxicology studies (BD: May 25, Aug 3, 2021).

Today, Paradigm said that the FDA advised that its responses "sufficiently addressed the questions raised".

The company said that central US ethics committee approval had been received and it was undertaking US site initiation, with patients to begin screening in the US and Australia by the end of the year.

Paradigm said that the first four of eight Australian sites had been initiated, with the remaining sites expected to be initiated by the end of the year, with 10 sites in Europe and the UK identified and expected to be initiated by July 2022.

the potential for trials in EU member countries.

The company said that the trial was a two-stage, adaptive, randomized, double-blind, placebo-controlled study evaluating the dose and treatment effect of 2mg/kg pentosan polysulfate sodium (PPS) injected weekly and a lower dose injected twice weekly and a fixed stratified dose pending weight weekly and placebo in patients with pain associated with knee osteoarthritis all for six weeks.

Paradigm said that the primary endpoint would be change from baseline at day-56 in the Western Ontario and McMaster Universities Osteoarthritis Index Womac pain score, with secondary outcomes including the change from baseline at time points to day-168 in Womac pain and function scores as well as patient global impression of change and quality of life.

The company said that an observational study was designed as a follow-up to the trial, evaluating the duration of treatment effect and safety up to 60 weeks following first injection with PPS.

Paradigm said its previous phase IIb study followed patients to day-165, so the follow-up study would provide additional data on the duration of effect of PPS over 12 months.

In 2018, Paradigm said that its 112-patient, phase IIb trial showed that injected pentosan polysulfate sodium significantly reduced knee osteoarthritis pain compared to placebo ($p = 0.031$) (BD: Dec 18, 2018).

Paradigm interim executive chair Paul Rennie said that "the opening of the trial in the USA, the largest global pharmaceutical market, is a major milestone".

"This milestone represents a substantial de-risking of the company's lead clinical program and is a testament to the company's expertise, commitment and determination," Mr Rennie said.

"As the company progresses with the trial, we expect there will be increasing interest from the pharmaceutical industry in the commercial value of this potential blockbuster therapeutic," Mr Rennie said.

Paradigm said that clearance to begin the trial was supported by 26 non-clinical studies, including studies on the tolerance profile of PPS, its pharmaco-kinetics profile and information needed to formulate an initial dose-finding stage designed to identify the minimal effective dose.

Paradigm was up 47 cents or 22.8 percent to $2.53 with 8.1 million shares traded.

MTP CONNECT

MTP Connect says its voucher scheme will award a total of $450,000 to five Western Australian companies to accelerate the manufacturing of medical products.

MTP Connect said the scheme was matched with $600,000 in cash co-contributors, taking the total to $1 million for Western Australia's biotechnology sector.

The Federally-funded MTP said the voucher initiative was announced by Western Australia Minister for Health and State Development, Jobs and Trade Roger Cook and was made available through the MTP Connect Western Australia Life Sciences Innovation Hub, which was co-funded by MTP Connect, the University of Western Australia and the Western Australia Government through the New Industries Fund.

The company said the awardees included Proteomics International for manufacturing its next generation device to predict diabetic kidney disease, Oncores Medical for its breast cancer surgery imaging device, Syngenis Pty Ltd for certified oligonucleotide manufacturing, Veintech Pty Ltd's Veinwave cannulation technology and Vitaltrace Pty Ltd for pre-production manufacturing of its childbirth biosensors

Proteomics said it was awarded $100,000 under the voucher scheme and would use the funding to support the manufacture of Promarkerd predictive test for diabetic kidney disease and other diagnostic tests and to establish additional quality control processes for manufacture of the immunoassay version of the Promarkerd test.

MTP Connect managing-director Dr Dan Grant said manufacturing medical products was a "national priority so we're supporting these promising projects to develop their medical devices and diagnostics".

"Each project is aiming to improve the health and wellbeing of Australians and if we can help them along the commercialization pathway through our voucher initiative, these companies will also continue contributing to the state's burgeoning innovation ecosystem," Dr Grant said.

MTP Connect said the projects were due to be completed by May 30, 2022.

MEDLAB CLINICAL

Medlab says the Department of Industry, Science, Energy and Resources has approved a $26,981,176 off-shore Research and Development Tax Incentive claim.

Medlab said the advanced and overseas finding related to the development of its synthetic marijuana based Nanabis for cancer bone pain for the three years to 2023.

Medlab chief executive officer Dr Sean Hall said the approval would "directly support the company's go-forward program for Nanabis with a 43.5 percent cash rebate expected on the overseas expenditure in the advanced overseas finding".

Medlab was up half a cent or 3.2 percent to 16 cents.

CORRECTION: BARD1 LIFE SCIENCES

Monday's edition reported incorrect exercise prices for the proposed issue of 2,000,000 options to four directors at the November 29 annual general meeting.

Bard1 has told Biotech Daily that the options would vest in equal tranches, on reaching a 7-day volume-weighted average price of $2.32 and exercisable at $2.32 by September 30, 2023, and the second tranche on reaching a 7-day VWAP of $3.00, exercisable at $3.00 by September 30, 2024, not as reported.

Biotech Daily apologizes unreservedly for the error and has terminated the Monday annual general meetings sub-editor with extreme prejudice.

Bard1 fell three cents or 2.9 percent to 99 cents.

MEMPHASYS

Memphasys says it has completed verification and validation assessments for the Felix sperm separation device.
In March, Memphasys said a flaw was found in the validation process and would delay production and commercial sales and in September said Hydrix agreed to pay $500,000 and issue 1,000,000 Hydrix shares for the rectification of a flaw (BD: Mar 8, Sep 1, 2021).
Today, the company said verification confirmed specified design requirements and validation confirmed the specific intended use, with both required for commercial sales.
The company said that 25 in-vitro samples per “key opinion leader” had been “positive and in-line with Memphasys’ expectations”.
Memphasys said the preliminary results demonstrated the device’s ability to rapidly and consistently select cells with low levels of DNA fragmentation and could be used with a wide range of semen samples, including viscous samples and samples with low sperm counts, poor motility and high DNA fragmentation levels.
The company said commercial discussions were underway with its key opinion leaders.
Memphasys executive chair Alison Coutts said the company believed that “a maiden commercial sale can be made prior to the end of the calendar year”.
Memphasys was up 1.6 cents or 26.7 percent to 7.6 cents with 12.4 million shares traded.

LUMOS DIAGNOSTICS

Lumos says Canada Health has granted interim authorization for its Covidx severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) rapid antigen test.
Lumos said the Covidx test would give qualified healthcare providers “qualitative, easy to interpret results within 15 to 20 minutes” in suspected asymptomatic Covid-19 patients.
Lumos chief executive officer Dr Rob Sambursky said that rapid, point-of-care testing was “a critical component of the Canadian public health response”.
“Using Covidx as part of routine testing and triage protocols can help advance public health and safety in Canada,” Dr Sambursky said.
Lumos said the standalone point-of-care test used individual pre-filled extraction reagent vials to make it easy to administer in any patient care setting, without additional instruments or equipment, and was compatible with both nasopharyngeal and the less invasive nasal swab sample collection and provided a simple yes or no result.
Lumos said that a previous trial showed 100 percent sensitivity and 95 percent specificity in patients with cycle threshold counts below 35 within five days of symptom onset”.
Lumos was up 1.5 cents or 1.75 percent to 87 cents.

BCAL DIAGNOSTICS

BCal claims analysis of 301 patient samples for early-stage detection of breast cancer has produced “positive results” and is recruiting patients for a clinical trial of its test.
BCal said the clinical data was “in alignment with previously reported specificity and accuracy of the test in early-stage detection of breast cancer” but did not disclose the data, based on an 18-candidate lipid marker panel.
The company said it would refine its algorithm and biomarker development and had appointed a consulting group to assist with algorithm optimization.
BCal said it was recruiting patients for a trial of the breast cancer test with 150 patients secured at sites including the Sydney Breast Clinic and Chris O’Brien Lifehouse, with recruitment at Breastscreen New South Wales to begin following the Covid-19 lockdown.
BCAL was unchanged at 15.5 cents.

NUHEARA

Nuheara says it has been appointed as an accredited service provider to the Australian Government Hearing Services Program.

Nuheara said the service provider accreditation meant it could offer products through the Program, including the supply of products, telehealth consultations with trained and qualified audiologists and the dispensing of products directly to voucher holders.

The company said the products and services dispensed to voucher holders were rebated to Nuheara by the Federal Government.

Nuheara said the accreditation complemented its status as an approved manufacturer for the Iqbuds2 Max as an assisted listening device.

Nuheara fell 0.1 cents or 4.8 percent to two cents with 8.8 million shares traded.

USCOM

Uscom says it will provide its Spirosonic Air lung diagnostic “direct wireless integration of data” to the New York-based Koneska’s platform.

Uscom said its research and development team had developed high level spirometry algorithms and programs applications “to allow the breath-to-breath delivery of precise respiratory function data using Spirosonic Air sensors.

The company said Koneska specialized in the collection and analysis of biometric data for pharmaceutical and biotechnology trials, as well as digital monitoring of multiple physiologic parameters.

Uscom chair Rob Phillips told Biotech Daily that the relationship between the two companies had been informal “over the last two years”.

Uscom was untraded at 12.5 cents.

ARGENICA THERAPEUTICS

Argenica says ARG-007 reduces the volume of brain tissue death caused by late pre-term hypoxic-ischaemic encephalopathy by 50 percent compared to saline, in rats.

Argenica said hypoxic-ischaemic encephalopathy (HIE) was caused when the brain did not receive enough oxygen or blood flow.

The company said the study at the Perth, Western Australia’s Perron Institute for Neurological and Translational Science explored the neuro-protective properties of ARG-007 when administered immediately following hypoxia-ischaemia in perinatal rats, equivalent to late pre-term human infants.

Argenica said ARG-007 reduced the volume of brain tissue death by 40 percent compared to hypothermia which was the current standard-of-care and the only approved treatment to improve neurological outcomes of hypoxic-ischaemic encephalopathy for late pre-term and term infants.

Argenica said the findings from the study were being prepared for publication and would become the foundation for additional efficacy studies of ARG-007 in additional animal models of hypoxic-ischaemic encephalopathy.

Argenica chief executive officer Dr Liz Dallimore said the data “further confirms the neuroprotective capability of ARG-007 in infant HIE, which is extremely encouraging”. “We now have a number of positive preclinical rodent models in HIE confirming the efficacy of ARG007 to significantly protect brain cells from injury,” Dr Dallimore said.

“This data is important because it shows that ARG-007 may have a greater application moving forward than just in the area of stoke patients,” Dr Dallimore said.

Argenica was up 2.5 cents or 6.6 percent to 40.5 cents.

RACE ONCOLOGY

Race says it will work with the University of Newcastle to develop a companion diagnostic for Zantrene, formerly bisantrene, for acute myeloid leukemia.
Race said the project, titled 'Genome-wide epitranscriptomic analysis of N6-methyl-adenosine modification at nucleotide resolution using RNA sequencing to identify biomarkers of aberrant tumour RNA methylation' would target fat mass and obesity associated protein (FTO) and be led by the New South Wales University of Newcastle's Prof Murray Cairns.
The company said the project would use RNA genomics technologies to identify biomarkers of Zantrene sensitivity in human cancer cells and tissue samples.
The company said the preclinical research program would start immediately with results to be reported over the next 12 months.
Race fell six cents or 1.8 percent to $3.31.

ZELIRA THERAPEUTICS

Zelira says its "distillate capture and dissolution matrix" will help develop pharmaceutical grade doses of marijuana and it has a deal with DRCN.
Zelira said it had an agreement with the Delaware-based DRCN Holdings LLC, including an upfront, non-refundable, non-contingent licencing fee of $US1 million ($A1.35 million), and DRCN would have up to three years to develop up to three commercial products using the Zelira enhanced distillate capture and dissolution matrix (EDCDM) technology, with a 20 percent royalty on net sales from products.
The company said that the matrix-based cannabinoid capsules had an "enhanced dissolution profile" and the technology "solves the problem of non-uniformity and separation of cannabinoid from powder bed".
Zelira was up 0.4 cents or 10.5 percent to 4.2 cents with 5.3 million shares traded.

MGC PHARMACEUTICALS

MGC says it has completed construction and the implementation phase of its Cimetra production factory in Malta.
MGC said it received an EUR3.1 million ($A4.8 million) cash grant through Malta Enterprise to fund the majority of the costs of construction and equipment.
MGC was up 0.2 cents or 4.3 percent to 4.9 cents with 2.65 million shares traded.

COCHLEAR

The Malvern, Pennsylvania-based Vanguard Group says it has ceased its substantial shareholding in Cochlear, but holds 4.969 percent.
Last week, Vanguard Group said it became a substantial shareholder in Cochlear with 3,289,139 shares or 5.001 percent.
Today, the company said it bought and sold shares at prices ranging from $219.96 to $228.54 a share.
Cochlear was up $1.36 or 0.6 percent to $227.66 with 73,967 shares traded.