Biotech Daily

Wednesday October 19, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: UNIVERSAL BIOSENSORS UP 11.5%; NOVA EYE DOWN 14%**

*** GARVAN RECRUITING PHASE III METFORMIN COGNITION, DEMENTIA TRIAL**

*** PHARMAXIS PLACEMENT TO RAISE $10m**

*** RADIOPHARM RIGHTS OFFER FOR $10m**

*** TEVA AUSTEDO 'BENEFIT FOR HUNTINGTON'S CHOREA'**

*** CRONOS POSTS RECORD $26m Q1 REVENUE**

*** PHARMAXIS INTERIM DATA BACKS PXS-5505 FOR MYELOFIBROSIS**

*** LUMOS FEBRIDX BACTERIAL, VIRAL RESPIRATORY INFECTION DATA**

*** MICROBIO: ECUADOR EVALUATES INFECTID-BSI BLOOD TEST**

*** 4D APPLIES FOR CATEGORY III XV LVAS CPT CODE**

*** ABL TO MANUFACTURE VAXINIA FOR IMUGENE TRIALS**

*** NEXT SCIENCE COMBINES COLLAGEN WITH BLASTX**

*** ANATARA REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** ALIUM ALPHA BELOW 5% IN MICROBA**

*** AROVELLA 10m 'IN LIEU' DIRECTOR OPTIONS, 1.6m M-D SHARES AGM**

*** MEDADVISOR: KEVIN HUTCHISON US DIRECTOR; LOSES ROBERT READ**

MARKET REPORT

The Australian stock market was up 0.31 percent on Wednesday October 19, 2022, with the ASX200 up 20.9 points to 6,800.1 points. Twenty of the Biotech Daily Top 40 were up, 14 fell, five traded unchanged and one was untraded. All three Big Caps were up.

Universal Biosensors was the best, up three cents or 11.5 percent to 29 cents, with 111,257 shares traded. Compumedics, Medical Developments and Uscom climbed more than eight percent; Oncosil and Prescient were up more than five percent; Actinogen and Next Science improved more than four percent; Atomo, Cynata, Impedimed, Mesoblast, Telix and Volpara were up three percent or more; Clinuvel rose 2.1 percent; Cochlear, Nanosonics, Orthocell, Pro Medicus and Proteomics were up more than one percent; with CSL, Neuren and Resmed up by less than one percent.

Nova Eye led the falls, down 3.75 cents or 14.0 percent to 23 cents, with 20,007 shares traded. Pharmaxis fell 7.7 percent; Dimerix was down 6.1 percent; Cyclopharm lost 5.4 percent; Patrys fell 4.8 percent; Micro-X was down 3.6 percent; Imugene, Kazia and Paradigm shed more than two percent; Avita, Emvision, Opthea and Polynovo were down one percent or more; with Starpharma down 0.8 percent.

THE GARVAN INSTITUTE OF MEDICAL RESEARCH

The Garvan Institute says it wants participants for a 240-patient, phase III trial of metformin on cognition, brain anatomy, vascular health and early signs of dementia.
A Garvan spokesperson told Biotech Daily that the randomized, controlled trial had recruited about 60 participants and was hoping to recruit a further 180 people.
The Institute said it was looking for participants "aged over 60 years, living in the Greater Sydney region and experiencing symptoms of mild cognitive impairment like challenges with memory loss and thinking".
The Garvan said that metformin "could slow the process of cognitive decline, a hallmark of the processes that may lead to dementia".
The Institute said that metformin was used to treat diabetes and other metabolic disorders, was approved by the Australian Therapeutic Goods Administration and was "one of the most commonly prescribed medications, globally".
The Garvan said that metformin had been used "to safely and cheaply treat patients with type 2 diabetes for around 60 years, by reducing the amount of glucose released by the liver and helping cells to better respond to blood-glucose levels".
The Institute said that the lead researcher Prof Katherine Samaras conducted a six-year study and found "that people with type 2 diabetes taking metformin showed much slower cognitive decline and had reduced rates of dementia development, compared to those not taking the drug".
"We are building on promising research on the positive effects of metformin that could have real impact on reducing or stopping the progress of cognitive decline, something for which there is no effective treatment," Prof Samaras said.
"It's thought that metformin assists the body in regulating the actions of insulin, thereby helping the brain to function better," Prof Samaras said. "We want to find out if these effects are seen in people with normal glucose metabolism."
The Garvan Institute said that if the 'Metmemory' "trial was successful "treatment for slowing cognitive decline could be immediately available".
The Institute said that previous research indicated that metformin had health benefits for cancer, heart disease, polycystic ovary syndrome and weight management.
For more information, go to: www.garvan.org.au/metmemory.

PHARMAXIS

Pharmaxis says it hopes to raise $10 million in a two-tranche placement to institutional investors at six cents a share.
Pharmaxis said the six cents placement price was a discount of 23.1 percent to the last closing price of 7.8 cents on October 17, 2022.
The company said the capital raised would be used in the current clinical study in myelofibrosis and other clinical studies that were open or due to begin in scarring, liver cancer and Parkinson's disease, as well as general working capital.
Pharmaxis chief executive officer Gary Phillips said "the positive preliminary data from Pharmaxis phase II clinical study in myelofibrosis has impressed global clinical experts and has driven interest from the specialist healthcare investors who have participated in this capital raise".
Pharmaxis said that Morgans Corporate and Bell Potter securities were joint lead managers and bookrunners for the placement.
The company said the placement would be conducted in two tranches, with the second requiring shareholder approval at the annual general meeting on November 29, 2022.
Pharmaxis fell 0.6 cents or 7.7 percent to 7.2 cents with 1.5 million shares traded.

RADIOPHARM THERANOSTICS

Radiopharm says it hopes to raise $10 million in a one-for-3.55, non-renounceable, institutional and retail entitlement offer at 14 cents a share.
Radiopharm said each share purchased would come with an attaching option exercisable at 20 cents each by November 30, 2026.
The company said that chair Paul Hopper would subscribe for $500,000 under the offer and chief executive officer Riccardo Canevari had subscribed for about $170,000 in shares.
Radiopharm said that offer price of 14 cents was an 18.9 percent discount to the 30-day volume weighted average price (VWAP) and a 15.2 percent discount to the last traded price of 16.5 cents.
The company said that the institutional component was being conducted today, October 19, 2022, with the record date for the retail component October 21, the offer would open on October 25, and close on November 11, 2022.
Radiopharm said the proceeds would provide a “runway until at least the end of 2023”.
The company sad that Bell Potter Securities was the sole lead manager with Baker Young the co-manager.
Radiopharm was in a suspension for the institutional offer and last traded at 16.5 cents.

TEVA PHARMACEUTICAL INDUSTRIES

Teva says its 119-patient, three-year extension trial of Austedo shows it is safe, tolerable and “improved or maintained chorea control” in Huntington’s disease/
Teva said it used the unified Huntington’s disease rating scale total maximal chorea score to determine the efficacy of Austedo, or deutetrabenazine, in chorea control over the three-year trial extension.
The company said that in 82 patients who were in the previous pivotal study, there was a 4.5-point reduction in mean chorea scores, and a 7.1-point reduction in total motor score from baseline to week-8 of the extension trial.
Teva said that in the 37 patients who switched from tetrabenazine to Austedo for the extension, there was a 2.1-point reduction in mean chorea scores and a 2.4-point reduction in mean total motor score from baseline to week-8.
The company said that reductions in chorea scores were maintained from week eight through to the end of treatment.
Teva said chorea was associated with “involuntary, random and sudden, twisting and/or writhing movements” and could interfere with daily function, cause social isolation, and increased risk of injury in Huntinton’s disease patients.
Teva head of specialty research and development Dr Eran Harary said chorea was “one of the most striking physical manifestations of Huntington’s disease that occurs in approximately 90 percent of Huntington’s disease patients”.
Lead author Dr Samuel Frank said the data provided “important insight into the long-term use of deutetrabenazine for the treatment of chorea associated with Huntington’s disease, which can have a significant functional impact on people’s lives”.
“Results of this study add to the safety and tolerability profile and support deutetrabenazine as a treatment choice for this progressive condition,” Dr Frank said.
Teva said that Austedo was the first and only vesicular monoamine transporter 2 (VMAT2) inhibitor approved by the US Food and Drug Administration for the treatment of tardive dyskinesia in adults and for the treatment of chorea associated with Huntington’s disease.
On the Nasdaq, Teva was up 13 US cents or 1.6 percent to $US8.31 ($A13.19) with 6.6 million shares traded.

CRONOS AUSTRALIA

Cronos says cash receipts for the three months to September 30, 2022 were up 13 percent to a record $25,949,286.
In December, Cronos said it had completed its merger with CDA Health Pty Ltd (formerly Cannabis Doctors Australia) (BD: Dec 16, 2021).
Today, Cronos said units of cannabis sold through its Canview platform increased 30 percent on the previous quarter to 214,000 units, bringing total units sold since the launch in mid-2021 to 830,000 units.
Cronos fell half a cent or 0.5 percent to 92.5 cents with 1.5 million shares traded.

PHARMAXIS

Pharmaxis says interim data from its phase II trial of PXS-5505 for myelofibrosis suggests an “excellent safety profile with encouraging signs of clinical activity”.
Pharmaxis said the 24-patient trial aimed to show that PXS-5505 was safe and effective as a monotherapy in myelofibrosis patients who were intolerant, unresponsive or ineligible for treatment with approved janus kinase inhibitor drugs.
Pharmaxis said 15 patients had been enrolled in the cohort expansion phase of the study with six patients completed 24 weeks of treatment, with four patients having “dropped out of the study due to a lack of clinical response”.
The company said PXS5505 was “well-tolerated with no serious treatment related adverse events reported”.
Pharmaxis said that two of six patients had “clinically important improvement in symptoms”, five of six patients had stable or improved bone marrow fibrosis scores, with five of six having stable or improved platelet or haemoglobin scores.
Pharmaxis said no reductions were seen in spleen volume.
The company said it expected the trial to be fully recruited by the end of this year, with results by October 2023.

LUMOS DIAGNOSTICS

Lumos says it has published results of a 496-person trial of its Febridx system to differentiate bacterial from viral acute respiratory infections.
Lumos said Febridx had a sensitivity of 93.2 percent and specificity of 88.4 percent for bacterial infections, providing a negative predictive value of 98.7 percent.
The company said that for viral infections, it had a sensitivity of 70.3 percent and specificity of 88.0 percent, with a negative predictive value of 66.7 percent.
Lumos said the study, titled ‘Diagnostic accuracy of a bacterial and viral biomarker point-of-care test in the outpatient setting’ was published in the Jama Open Network and was at: https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2797455.
Lumos chief executive officer Doug Ward said “the publication of this important clinical study in Jama reflects the quality of clinical data supporting our Febridx product.”
“While we were clearly disappointed with the recent outcomes of our regulatory application and appeal to the US Food and Drug Administration for clearance to market Febridx in the US, we continue to believe that it has an important role in global healthcare,” Mr Ward said.
Lumos was up 0.4 cents or eight percent to 5.4 cents.

MICROBIO

Brisbane's Microbio says it has started commercial evaluation trials of its Infectid-BSI bloodstream infection test in Ecuador, prior to a South American launch.
In August, Microbio said it had a UK Conformity Assessed (UKCA) marking, allowing it to sell the Infectid-BSI test in the UK (BD: Aug 16, 2022).
In July, the company said it was raising $3 million to commercialize the Infectid-BSI bloodstream infection test "to detect 26 of the most common sepsis-causing bacteria and fungi in less than three hours" (BD: Jul 6, 2022).
Today, the founder of the Guayaquil, Ecuador-based Ecuagenoma Labs Dr Hector Zambrano said he hoped to gain the appropriate regulatory clearance to market Infectid-BSI in Ecuador "before the end of this year".
"I have worked in molecular diagnostics for over a decade and have never come across anything close to Microbio's Infectid assays," Dr Zambrano said.
"Infectid as a technique and Infectid-BSI as a product is ground-breaking and better than the current gold-standard diagnostic tests for sepsis and bloodstream infections," Dr Zambrano said.
"The market and medical community have wanted something like this for a very long time," Dr Zambrano said.
"I've seen first-hand the enormous potential of Infectid-BSI to solve actual clinical problems that we face regularly all over the world," Dr Zambrano said.
"There is such a difference in timing, sensitivity and specificity when using Infectid-BSI as opposed to the current gold-standard," Dr Zambrano said.
"We have even been able to identify pathogens in blood samples that we could not previously identify," Dr Zambrano said,
Microbio said the test could be administered on quantitative polymerase chain reaction equipment, present in most diagnostic laboratories.
Microbio co-founder and chief scientific officer Dr Flavia Huygens said the Infectid-BSI had "the potential to significantly advance the detection of bloodstream infections and sepsis, one of the world's biggest killers".
"With the test being cleared for sale and use in Europe and now the UK, we are working to get Infectid-BSI cleared in Ecuador, across South America, and in the Caribbean," Dr Huygens said.
Dr Huygens said the current method to identify a causative pathogen was a two-step blood culturing and identification process taking 12 hours to several days with limited sensitivity, whereas the Infectid-BSI "significantly improves patient outcomes by alerting clinicians within three hours of taking a blood sample which infection to treat".
Microbio is a public unlisted company.

4D MEDICAL

4D Medical says it has applied to the American Medical Association for category III current procedural terminology (CPT) code for its XV lung ventilation analysis software (LVAS).
4D said that category III CPT codes "enable the assessment, and can establish the payment of, new services and procedures" as distinct from other technologies.
The company said CPT codes were a national, standardized system that US healthcare providers used to report medical services and procedures under public and private health insurance programs.
4D said the category III CPT code was "a critical milestone" for its XV LVAS to become a fully commercialized and reimbursable product in the US.
4D Medical was up five cents or 8.6 percent to 63 cents.

IMUGENE

Imugene says it has a five-year agreement with the Rockville, Maryland-based ABL Biomanufacturing to manufacture its oncolytic virus for its Vaxinia trials.
Imugene said ABL was a subsidiary of the Lyon, France-based Institute Mérieux and would deliver the first batch of Vaxinia within 12 months.
The company said that ABL would manufacture the oncolytic virus for its metastatic advanced solid tumors (Mast) studies evaluating the safety and efficacy of the cancer-killing virus CF33-hNIS, or Vaxinia.
Imugene managing-director Leslie Chong said “Reliability of drug supply is a major hurdle for the clinical development of many modern biological oncology drug candidates.”
“De-risking this critical component of clinical development by working with ABL is a significant milestone for Imugene,” Ms Chong said.
Imugene fell half a cent or 2.8 percent to 17.5 cents with 15.1 million shares traded.

NEXT SCIENCE

Next Science says it has launched a range of collagen products for use with its Blastx anti-microbial gel.
Next Science said it was also developing an integrated Blastx Collagen product to “fully preserve the efficacy of both Blastx and collagen” and intended to submit a 510(k) application to the US Food and Drug Administration.
The company said that it would conduct a user study on the combination of Blastx with collagen to provide “clinical evidence for the combined use of the two wound care technologies”.
Next Science said Blastx would be provided to patients in the user study who were prescribed collagen treatment “to add proven infection control to their healing strategy”.
The company said that case studies had shown that augmenting collagen treatment with Blastx pushed “a stalled surgical wound or unhealed pressure ulcer back to healing, with wound closure shown to occur at between two and four weeks”.
“Standard wound care healing usually takes between 12 and 16 weeks,” Next Science said.
The company said that as part of this submission, it had registered as a durable medical equipment manufacturer with US Medicare.
Next Science said that durable medical equipment manufacturer status would allow it to “expand its wound care business footprint, substantially”.
Next Science was up 3.5 cents or 4.7 percent to 77.5 cents.

ANATARA LIFESCIENCES

Anatara has requested a trading halt “pending an announcement … in relation to a capital raising”.
Trading will resume on October 21, 2022.
Anatara last traded at 4.6 cents.

MICROBA LIFE SCIENCES

Sydney’s Alium Alpha Fund says it has sold 1,286,794 shares (0.47%) for an undisclosed price and reduced its substantial holding below the five percent substantial level.
In August, Alium said it held 14,985,993 Microba shares (5.46%) (BD: Aug 24, 2022).
Microba was up one cent or 6.9 percent to 15.5 cents.

AROVELLA THERAPEUTICS

Arovella says investors will vote to issue directors 10,400,000 options in lieu of pay and 1,586,842 shares to managing-director Dr Michael Baker, in lieu of a cash bonus.
Arovella the shares for Dr Baker were in lieu of a cash bonus and the director options were in lieu of 50 percent of their directors' fees.
The company said the annual general meeting would vote to issue 4,800,000 options to interim chair Dr Elizabeth Stoner, with 2,400,000 options to directors Dr Deborah Barton and 1,600,000 options each to directors Gary Phillips and David Simmonds, all exercisable at a 120 percent premium to the 30-day volume-weighted average share price to the date of issue, and within five years.
Arovella said shareholders would vote to adopt the remuneration report, elect Mr Phillips as, approve the 10 percent placement facility and ratify the prior issue of stock to Oschie Capital, Merchant Group Australia, S3 Consortium and Spark Plus.
The meeting will take place at The CFO Solution, Level 3, 62 Lygon St, Carlton South, Victoria, on November 17, 2022 at 11.30am (AEDT) and virtually with registration at: https://us02web.zoom.us/webinar/register/WN_IlgSgqSzR_2QarqGOMMS-w.
Arovella was up 0.1 cents or 3.3 percent to 3.1 cents.

MEDADVISOR

Medadvisor says it has appointed Kevin Hutchison as a US-based non-executive director, effective from November 23, 2022, with Robert Read leaving a week later.
Medadvisor said Mr Hutchison was currently working with Abundant Venture Partners, managing AXL Health and previously worked for healthcare technology start-ups and growth stage ventures, including as the founding chief executive officer of Surescripts.
The company said Mr Hutchison held a Bachelor of Business Administration from the University of Oklahoma.
Medadvisor said that Mr Read would leave the company after the November 30 annual general meeting (BD: Apr 6, 2022).
Medadvisor was unchanged at 14.5 cents.