Biotech Daily

Wednesday March 6, 2024

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: DIMERIX UP 27%; RESONANCE DOWN 10%**

*** UNIVERSITY OF NSW 'POCKET PCR' RAPID ANTIGEN TEST**

*** LA TROBE, HEALTHSCOPE PRIVATE HOSPITAL RESEARCH FACILITIES**

*** ALCIDION $3.4m NHS MIYA CONTRACT EXTENSION**

*** ATOMO RECEIVES $970k HIV SELF-TEST ORDER**

*** NYRADA 'COMMITMENTS' FOR $2m PLACEMENT**

*** IMRICOR VISION-MR CATHETER WINS CE MARK**

*** CLARITY: 'CU-64-SAR-BIS-PSMA CAN DETECT 2mm CANCER LESIONS'**

*** ADALTA AD-214 PHASE I EXTENSION STUDY FINDS 'SAFE' PHASE II DOSE**

*** RACE: 'LOW-DOSE BISANTRENE ACTIVE AGAINST AML, IN MICE'**

*** PROTEOMICS RETAINS ISO13485 CERTIFICATION**

*** RADIOPHARM TO PRESENT RAD301 DATA**

*** INHALERX IRX211 DATABASE LOCK A MARIJUANA 'MILESTONE'**

*** BCAL COO SHANE RYAN REPLACES CEO DR JOHN HURRELL; ON $350k PA**

MARKET REPORT

The Australian stock market was up 0.12 percent on Wednesday March 6, 2024, with the ASX200 up 9.3 points to 7,733.5 points. Thirteen of the Biotech Daily Top 40 stocks were up, 21 fell, five traded unchanged and one was untraded.

Dimerix was the best, up six cents or 27.3 percent to 28 cents, with 19.0 million shares traded. Atomo climbed 14.8 percent; Actinogen was up 6.7 percent; Genetic Signatures, Impedimed and Mesoblast improved more than three percent; SDI rose 2.45 percent; Emvision and Percheron (Antisense) were up more than one percent; with Cochlear, Neuren, Polynovo, Proteomics and Volpara up by less than one percent.

Resonance led the falls, down 0.6 cents or 9.8 percent to 5.5 cents, with 691,707 shares traded. Compumedics lost 6.8 percent; Cynata and Next Science were down five percent or more; Avita, Imugene, Medical Developments, Nanosonics and Syntara (Pharmaxis) fell more than four percent; 4D Medical, Clinuvel, Starpharma and Universal Biosensors were down more than three percent; Immutep, Nova Eye, Opthea, Orthocell and Telix shed more than two percent; Clarity, Cyclopharm and Resmed were down more than one percent; with CSL and Pro Medicus down by less than one percent.

UNIVERSITY OF NEW SOUTH WALES

The University of New South Wales says it has developed a rapid antigen test that is “just as accurate as the lab-based [polymerase chain reaction] tests”.

A media release from the University of New South Wales said that bio-medical engineers at its Sydney campus developed a technology using “tiny DNA nano-circles containing a short sequence of the target DNA, such as the Covid-19 virus”.

The University said the DNA nano-circles were about two nanometres in size and were combined with the tested sample and mixed with Crispr-Cas, or clusters of regularly interspaced short palindromic repeats (Crispr)-associated, proteins to form a molecular chain reaction that cuts the DNA of the nano-circles when activated by the DNA from the targeted pathogen.

The media release said the method had been illustrated in samples of Covid-19 and helicobacter bacteria that cause stomach ulcers.

The University said polymerase chain reaction tests required substantial and expensive logistics and had delayed results which increased the risk of disease spread.

The University of New South Wales said its rapid antigen test could offer rapid, on-the-spot disease detection and could have applications beyond public health including biomedical and environmental diagnostics in the food industry, agriculture and biosafety.

The University of New South Wales said the research, titled ‘Topological barrier to Cas12a activation by circular DNA nanostructures facilitates autocatalysis and transforms DNA/RNA sensing’ was published in Nature Communications, with the full article available at: https://www.nature.com/articles/s41467-024-46001-8.

The University of New South Wales researcher Prof Ewa Goldys said the test could “detect specific gene sequences in a sample … at room temperature using a test strip that looks exactly like a well-known Covid-19 [rapid antigen test]”.

Study author Dr Fei Deng said the test strips could accelerate the response to emerging pathogens such as mosquito-borne or lumpy skin diseases, reveal hotspots of antibiotic resistance or help look for threatened animal species.

“This could transform human and animal infection control as well as quarantine and bio-diversity conservation efforts,” Dr Deng said.

“We think we created a new benchmark in biosensing, our gene-based tests will be able to be performed anywhere, anytime, by virtually anyone,” Dr Deng said.

LA TROBE UNIVERSITY

La Trobe University says with Melbourne’s Healthscope it has opened its La Trobe Private Hospital for patient care, research and education at its Bundoora campus.

A media release from La Trobe University said the hospital provided students and researchers with opportunities to develop clinical skills, while offering better health outcomes for patients in Melbourne’s northern suburbs.

The University said the hospital was opened by the Federal Assistant Minister for Health and Ageing Ged Kearney following a $25 million re-development by Healthscope.

La Trobe said the 34-bed hospital focused on orthopaedics, general surgery, plastic surgery and urology, had four operating theatres and a four-bed high dependency unit, along with a radiology clinic and consulting suites.

The University said the hospital would deliver additional clinical education placement opportunities for students, along with boosting research capability.

La Trobe vice-chancellor Prof Theo Farrell said the hospital opening was “the latest milestone in … [the] ambitious University City of the Future which is transforming Melbourne’s north”.

ALCIDION GROUP

Alcidion says it has a $3.4 million contract extension with Kent, England's Dartford and Gravesham National Health Services (NHS) Trust for use of its Miya Precision platform.
Alcidion said the three-year extension included the use of its flow, access, command, observations, assessments, electronic noting and associated partner products.
The company said Dartford and Gravesham NHS Trust was the first Miya Precision implementation in the UK, and that the initial five-year contract from March 2019 covered electronic observations, assessments, clinical noting and patient flow.
Alcidion said that additional Miya Precision and partner modules, including Emergency Department and Order Comms, were added during the initial contract.
The company said that the contract extension would include a move to an internet 'cloud' delivery system.
Alcidion said that its Miya Precision had been used to support digitizing care including electronic observations, digital patient assessment and patient flow.
The company said that "the success of the modular approach positions [Dartford and Gravesham NHS Trust] well for future enhancement to its digital strategy".
Alcidion managing-director Kate Quirke said the company was "pleased to be able to extend the arrangement allowing [Dartford and Gravesham Trust] to continue to gain the value of improved patient flow and support for their clinical staff, ultimately benefitting patient care".
Alcidion was unchanged at 5.1 cents with 3.1 million shares traded.

ATOMO DIAGNOSTICS

Atomo says it has received a $970,000 order from partner Viatris Healthcare Pty Ltd for its HIV self-tests in low and middle income countries.
Atomo said the Mylan branded tests would be supplied to "a number of low and middle income countries" and manufactured by July 2024.
The company said it considered the revenue form the orders to be material.
Atomo managing-director John Kelly said the company had "seen growing demand during 2023-'24 for the Atomo HIV self-test here in Australia as well as across branded versions supplied to international markets".
"Following significant increases in sales to Europe and in Australia, it is good to now see emergent demand across [low-middle income country] markets from our global health partner for HIV testing, Viatris," Mr Kelly said.
Atomo was up 0.4 cents or 14.8 percent to 3.1 cents with 81.8 million shares traded.

NYRADA

Nyrada says it has "firm commitments" to place $1,755,000 at 7.5 cents per Chess depository interest, with directors subscribing for $210,000 more, subject to approval.
Nyrada said the placement price was a 26.1 percent discount to its 15-day volume weighted average price and the funds raised would be used for a pre-clinical study and a phase I clinical trial of NYR-BI03 for brain injuries, to begin before 2025.
Nyrada said Canary Capital Pty Ltd had acted as lead manager to the raise and would receive six percent of the total amount raised as well as 5,000,000 options exercisable at 13.5 cents each by June 30, 2027.
Nyrada fell 0.3 cents or 3.3 percent to 8.7 cents with 14.0 million shares traded.

IMRICOR MEDICAL SYSTEMS

Imricor says it has Conformité Européenne mark certification to sell its Vision-magnetic resonance imaging ablation catheter in the European Union.
Imricor said the certificate was granted under the European Union Medical Device Regulations, and allowed it to sell its lower-cost ablation catheter kit, which it estimated cost about 35 percent less to manufacture.
The company said that currently customers purchased a kit of two Vision-MR ablation catheters for each atrial flutter procedure, with one ablation catheter used for ablating and the other a diagnostic or reference catheter, and selling at a price reflecting what an ablation catheter plus diagnostic catheter would cost.
Imricor said the lower cost Vision-MR diagnostic catheter would replace the second ablation catheter in the kit, thereby improving margins for each procedure.
The company said it would begin manufacturing the Vision-magnetic resonance imaging ablation catheter in April.
Imricor chief executive officer Steve Wedan said the release of the Vision MR diagnostic catheter into the clinical market would “realise immediate margin improvements”.
Imricor fell 1.5 cents or 3.2 percent to 45 cents.

CLARITY PHARMACEUTICALS

Clarity says its phase I/II trial shows that copper-64 Sar-Bis-PSMA can detect “much smaller lesions than anticipated” including a lesion with a less than 2.0mm diameter.
Last month, Clarity said its 52-patient, phase I/II, non-randomized, open-label ‘Cobra’ imaging trial of copper-64 Sar-Bis-prostate specific membrane antigen (PSMA) showed it was “safe and highly effective in detecting tumors” (BD: Feb 15, 2024).
At that time, Clarity said same-day imaging identified 29 of 50 patients, or 58.0 percent, and next-day imaging identified up-to 40 of 50 patients, or 80.0 percent, with high specificity on both days and some lesions undetectable by standard-of-care.
Today, the company said one reason for the higher detection of lesions on next-day imaging was due to copper-64’s ability to detect much smaller lesions compared to other prostate specific membrane antigen agents.
Clarity said for all lesions, regardless of size, copper-64 lesion uptake increased by more than 80 percent and lesion contrast increased almost five times when comparing same-day to next-day imaging.
The company said the imaging agent had a “high uptake and contrast observed in lesions of less than 5.0mm” and that more lesions and smaller lesions detected on next-day imaging could have an impact on patient treatment.
Clarity said current positron emission tomography imaging agents had a lower sensitivity due to the challenge of detecting lesions that were less than 5.0mm in size.
The company said copper-64 could detect smaller lesions with next-day imaging due to its longer half-life compared to approved similar products.
Clarity chief executive officer Dr Alan Taylor said the difference between copper-64 and standard-of-care agents was “similar to comparing the old Hubble telescope to the new James Webb telescope, allowing us to visualize with much greater clarity, and to effectively change the paradigm of treatment to considerably improve … outcomes”.
“The ability of [copper-64 Sar-Bis-PSMA] to detect such small lesions is due to the higher uptake and retention of the product over time with high contrast,” Dr Taylor said.
“Small lesions become more readily detectable if the uptake … is high and the background noise on the image is low” enhancing contrast.
Clarity fell three cents or one percent to $2.85 with 565,946 shares traded.

ADALTA

Adalta says its phase I extension study of AD-214 for fibrotic diseases has established the safety and tolerability of the 10mg/kg dose for the planned phase II trial.

Last year, Adalta said that its eight-participant phase I extension study of AD-214 showed that three 10mg/kg doses had a similar “favorable tolerability profile” as lower doses, and later said it was ‘safe and well-tolerated’ (BD: Oct 23, Nov 21, 2023).

Today, the company said the study confirmed AD-214’s pharmaco-kinetics and engagement with its target receptor and that its pharmaco-dynamics were consistent with prior studies and consistent across all four doses and all participants.

Adalta said the results showed “no evidence of anti-drug antibody mediated or other effects that might detract from efficacy after extended use in diseases such as [idiopathic pulmonary fibrosis]”.

The company said the extension study of AD-214 had positively answered questions being asked by potential pharmaceutical company partners.

Adalta managing-director Dr Tim Oldham said the results “answered in the best way possible the key clinical questions large [pharmaceutical] company partners have been asking about AD-214”.

“With these questions answered, the molecule is now prepared for phase II clinical studies, a significant milestone for Adalta,” Dr Oldham said.

“We have already commenced the process of sharing these latest results with our potential partners with a view to progressing a licensing or asset financing transaction in the near term … [which] would enable AD-214 to advance to phase II clinical trials in idiopathic pulmonary fibrosis to provide a new option for patients with this debilitating and fatal disease as well as providing a return on our investment to date," Dr Oldham said.

Adalta was up 0.4 cents or 16.0 percent to 2.9 cents with 132.4 million shares traded.

RACE ONCOLOGY

Race says a study of its low-dose bisantrene with standard-of-care decitabine shows “potent anti-cancer activity” for primary acute myeloid leukaemia (AML), in mice.

In 2015, Race said Bisantrene had been approved in France for acute myeloid leukaemia but never launched because it was effectively “lost” in a string of pharmaceutical company mergers (BD: Aug 27, 2015).

In 2022, Race said the Houston, Texas-based MD Anderson Cancer Centre had shown bisantrene combination efficacy for acute myeloid leukaemia (BD: Feb 23, 2022).

Today, the company said New South Wales’ University of Newcastle researchers had shown a combination of bisantrene and decitabine “showed robust anti-cancer synergy in both cell and mouse acute myeloid leukaemia models”.

Race said the data supported clinical trials of its bistantrene formulation as a “low intensity treatment approach for [acute myeloid leukaemia] patients”.

The company said the data from the study, titled ‘Preclinical evaluation of bisantrene alone and in combination with decitabine for Acute Myeloid Leukaemia’ was presented at the New Directions Leukaemia Research conference in Adelaide from March 4 to 6, 2024, and was expected to be submitted for publication this year.

Race chief executive officer Dr Daniel Tillett told Biotech Daily that today’s announced pre-clinical work was “for the use of bisantrene at low doses, not the high doses used historically”.

“This means that bisantrene can potentially be used in two-thirds of acute myeloid leukaemia patients that are too ill to handle high intensity chemo,” Dr Tillett said.

Race was up five cents or 5.9 percent to 90 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has retained its International Organization for Standardization (ISO) certification for the safety and quality of its manufacturing of medical devices.
Proteomics said the iso13485 certification ensured patient safety the priority and “the consistent design, development, production, storage and distribution, installation or servicing and disposal of medical devices”.
The company said the re-certification would benefit future sales of its Promarkerd test for diabetic kidney disease and its strong pipeline of diagnostic tests being developed.
Proteomics managing-director Dr Richard Lipscombe said recertification was a “significant achievement, as it once again confirms the company has [a] solid quality management systems foundation”.
Proteomics was up one cent or 0.9 percent to $1.145.

RADIOPHARM THERANOSTICS

Radiopharm says it will present three data sets on RAD301 for cancer at the European Molecular Imaging meeting from March 12 to 15, 2024 in Porto, Portugal.
Radiopharm said RAD301, or 68-gallium-trivehexin, was a peptide-based molecule that targeted alpha-v-beta-6-integrin, a cellular marker for tumor invasion and metastatic growth which has been shown to correlate with decreased survival in several carcinomas, including pancreatic carcinoma cells.
The company said it would present the first data, titled ‘Efficient reduction of renal uptake of αvβ6-integrin targeted at Ga-68 PET imaging agents and Lu-177 therapeutics’ on March 13, 2024.
Radiopharm said the second and third data sets, titled ‘Preliminary results of a Phase 2 study: 68Ga-Trivehexin PET/CT of αvβ6-integrin expression in HNSCC and PDAC and correlation with ITGB6 expression’ and ‘Relevance of αvβ6-integrin as a theranostic target: In-depth immuno-histochemistry analysis of membranous ITGB6 expression in various human cancers’, would be presented on March 14 and 15, respectively.
The company said it would release each data set on the day of their presentation.
Radiopharm fell 0.1 cents or 1.5 percent to 6.4 cents.

INHALERX

Inhalerx says it “has achieved the milestone of database lock for the phase I clinical trial” of its inhaled marijuana-based IRX211 for breakthrough cancer pain.
Inhalerx said that the database lock was “the point at which the trial data [was] deemed as entirely complete” and it was notified by its contract research organization that the data was ready for statistical analysis.
The company said that a detailed clinical study report was expected in May 2024.
Inhalerx said it was preparing an application for ethics approval for a phase II efficacy and tolerability study of IRX211 compared to placebo for cancer pain.
Inhalerx chief executive officer Darryl Davies said the database lock for IRX211 was “a significant milestone in its development journey”.
“The preliminary analysis underscores the drug's promising efficiency and safety profile, across all doses studied,” Mr Davies said.
Inhalerx said it was “confident … [it would] be able to demonstrate the safety and tolerability of inhaled cannabidiol, which is already licenced for the treatment of rare paediatric-onset epilepsies and widely available as a non-prescription health supplement”.
Inhalerx was untraded at 4.5 cents.

BCAL DIAGNOSTICS

Bcal says chief operating officer Shane Ryan will replace Dr John Hurrell as chief executive officer, who will continue as a director, effective from April 2, 2024.

Last year, Bcal said it had appointed Mr Ryan as its chief operating officer, effective from September 21, 2023 (BD: Sep 5, 2023).

Today, the company said since his appointment as chief operating officer Mr Ryan had "clearly demonstrated that he will be the right leader to take the organization through market launch, and to ensure expansion and growth of the business".

Bcal said Mr Ryan's "commercial, product launch experience will be vital in ensuring a successful launch of Breastest in late 2024".

The company said Dr Hurrell would become a non-executive director and consultant to the company providing advice on the scientific product development, laboratory scaling, and commercial operations, as well as preparing for a subsequent US launch of its product.

Bcal said that Mr Ryan would be paid a base salary of $350,000 a year plus superannuation and be entitled to a short-term incentive of up to 50 percent of the salary pending milestones, as well as a long-term incentive of up to 2,000,000 performance rights, pending milestones.

Bcal fell 0.3 cents or 3.3 percent to 8.7 cents with 1.4 million shares traded.