Biotech Daily

Wednesday September 20, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: UNIVERSAL BIO UP 22%; STARPHARMA DOWN 9%**

*** DOHERTY, WEHI DEVELOP 'FASTER' MONKEYPOX TEST**

*** FEDERAL GOVERNMENT ORDERS $1.5m MICRO-X ROVERS**

*** BIOCURATE RENEWS TAKEDA PARTNERSHIP**

*** IMRICOR: PATIENT INFECTION DELAYS EU VISABL-VT TRIAL**

*** ADALTA ENROLS AD-214 EXTENSION STUDY**

*** CANN FURTHER $1.6m LEVIN HEALTH MARIJUANA DEAL**

*** BOTANIX PLEADS SCHULTZ, FDA DECISION TO ASX 23.5% RISE QUERY**

*** PROTEOMICS REQUESTS 'TEST APPROVAL' SUSPENSION EXTENSION**

*** FIL (FIDELITY) REDUCES TO 5% OF STARPHARMA**

*** BVF PARTNERS DILUTED TO 12% OF ACTINOGEN**

*** FIL TAKES 7.7% OF RECCE**

MARKET REPORT

The Australian stock market fell 0.46 percent on Wednesday September 20, 2023 with the ASX200 down 33.3 points to 7,163.3 points. Twelve of the Biotech Daily Top 40 stocks were up, 15 fell, 12 traded unchanged and one was untraded. All three Big Caps fell.

Universal Biosensors was the best, up five cents or 21.7 percent to 28 cents, with 266,051 shares traded. Compumedics climbed 19.4 percent; Impedimed improved 11.4 percent; Next Science was up 6.8 percent; Dimerix and Micro-X were up more than four percent; Cynata climbed 3.7 percent; Antisense, Opthea, Pro Medicus and SDI were up one percent or more; with Telix up by 0.8 percent.

Starpharma led the falls, down 1.5 cents or 8.8 percent to 15.5 cents, with 661,924 shares traded. Paradigm lost 8.15 percent; Avita shed 6.7 percent; Mesoblast fell 4.9 percent; Emvision and Neuren were down three percent or more; Medical Developments, Pharmaxis, Polynovo and Resmed shed more than two percent; Clinuvel, Nanosonics, Orthocell, Resonance and Volpara were down more than one percent; with 4D Medical, Cochlear and CSL down by less than one percent.

THE PETER DOHERTY INSTITUTE FOR INFECTION AND IMMUNITY
THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Doherty Institute says early studies show its monkeypox diagnostic detected the virus in samples with “acute precision and at a faster rate than any other method”.

The Doherty said the test, called monkeypox virus-clustered regularly interspaced short palindromic repeats (MPXV-Crispr), was “the first Crispr-based diagnostic method in Australia specifically designed to target genetic sequences found only in MPXV”.

The Institute said while Crispr technology was known for its genome-editing capability further applications had emerged “including leveraging it for the design of powerful and highly sensitive diagnostic tools”.

The Doherty said the study with the Walter and Eliza Hall Institute, titled ‘Rapid detection of monkeypox virus using a CRISPR-Cas12a mediated assay: a laboratory validation and evaluation’ was published in The Lancet Microbe and was available at: https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247(23)00148-9/fulltext.

The Institute said that researchers were working on adapting the MPXV-Crispr diagnostic into a portable device that could be deployed at points of care around the country for rapid, on-site detection of monkeypox virus.

Doherty Institute and University of Melbourne researcher officer and study co-author Dr Soo Jen Low said that Crisp-based diagnostic tools were like “super-precise detectives that can quickly find specific clues, in this instance, genetic material, related to the presence of specific pathogens”.

“To work, MPXV-Crispr has to be ‘programmed’ to recognize the virus,” Dr Low said.

“We used a database of 523 [monkeypox virus] genomes to carefully engineer ‘guides’ to bind to the specific part we are looking for on the viral DNA,” Dr Low said.

“In essence, when viral DNA is present in a clinical sample, the Crispr system is guided to the target and subsequently emits a signal to indicate the presence of the virus… our testing method can achieve sensitivity and precision levels comparable to the gold-standard [polymerase chain reaction] methods, but in a fraction of the time,” Dr Low said.

WEHI research assistant Matthew O’Neill said that “currently [monkey pox] diagnostics rely largely on centralized laboratory settings, where test results might not be available for up to several days after sample collection, depending on geographical and logistical considerations … MPXV-Crispr can detect the virus in just 45 minutes”.

MICRO-X

Micro-X says the Australian Government has ordered $1.5 million worth of its Rover x-ray systems.

Micro-X said the units were in inventory and would undergo final modifications in Adelaide before being delivered in early October 2023.

The company said it had shipped and invoiced $1.3 million worth of its mobile digital radiography systems for the three months to September 30, 2023, including its Rover Plus and Nano systems, with the Government’s order bringing the total to $2.8 million.

Micro-X said its x-ray products had significantly reduced size, weight and power requirements “enabling greater mobility and ease of use in existing x-ray markets and a range of new and unique security and defence applications”.

Biotech Daily asked Micro-X whether the order was from the Department of Defence or the Department of Health.

Micro-X said the order was “commercial in confidence” but said the Rovers were “registered to be used as a medical device”.

Micro-X was up half a cent or 4.35 percent to 12 cents with two million shares traded.

BIOCURATE

Biocurate says it has renewed its partnership with Takeda Pharmaceutical Co “to collaborate on projects advancing promising early-stage therapeutic research”.
In 2019, Biocurate said it would share commercial and scientific expertise with Tokyo’s Takeda to accelerate the discovery of therapeutics and drugs (BD: Oct 30, 2019).
At that time, the organization said Takeda would collaborate directly and through participation in Biocurate’s Industry and Scientific Advisory Committee to assess therapeutic candidates from Biocurate’s academic partners, the University of Melbourne and Melbourne’s Monash University.
Today, Biocurate said the partnership had increased “access to scientific and commercialization expertise, as well as exposure to candidate projects in key therapeutic areas for collaboration, including potential co-investment”.
Biocurate director of partnerships Dr Eric Hayes said “we have some of the world’s best medical research teams operating out of Victoria’s laboratories”.
“Takeda’s expertise will help ensure this research has the best possible chance of becoming therapies that improve people’s lives,” Dr Hayes said.

IMRICOR MEDICAL SYSTEMS

Imricor says its Netherlands catheter trial has been delayed due to its first patient developing a serious infection prior to the ventricular tachycardia ablation procedure.
Earlier this year, Imricor said it had Netherlands ethics approval for a 64-patient, safety and efficacy trial of its Vision-magnetic resonance imaging ablation catheter for ventricular tachycardia, to support its Conformité Européenne (CE) mark certification for the heart scan (BD: Aug 1, 2023).
Today, the company said the procedure was “tentatively planned for the week of August 28, but the patient developed a serious infection prior to the procedure” and was still being treated with antibiotics.
Imricor said more ventricular tachycardia candidates had been screened and that the Haga Hospital, in the Hague where the trial would be conducted, was widening its search for potential appropriate patients and reaching out to nearby hospitals.
The company said that while it believed the first case would take place “very soon” it could not predict exactly when.
Imricor chief executive officer and chair Steve Wedan said that in his experience “anytime physicians are performing a first in-human procedure, they are very particular when it comes to patient selection.”
“As cases progress, and routine workflows develop, this selectivity relaxes toward the full population of patients who meet the inclusion criteria,” Mr Wedan said.
“Obtaining approval for such an ambitious and ground-breaking clinical trial, with such a large number of investigational devices, was the most significant Imricor milestone achieved in recent history,” Mr Wedan said. “Now, we will enrol patients and provide them with state-of-the-art, radiation-free [interventional cardiac magnetic resonance imaging] ICMR-guided ablation treatment.”
“This is not like the first time we did any ablation inside the MRI in 2011,” Mr Wedan said.
“For Visabl-VT, we are simply ablating in a different area of the heart,” Mr Wedan said.
The company said it expected to expand the trial to other sites in the Netherlands before the end of the year, with German sites expected to be added upon approval, which was currently under review.
Imricor fell two cents or 3.5 percent to 55 cents.

ADALTA

Adalta says it has enrolled all eight healthy volunteers in its phase I safety extension study of AD-214 for fibrotic diseases, including idiopathic pulmonary fibrosis.
In August, Adalta said it had dosed the first of up-to eight-patients in its phase I extension study of AD-214 (BD: Aug 4, 2023).
Today, the company said every participant had received at least one dose of AD-214 or placebo, with four receiving three doses and no safety concerns reported so far.
Adalta said the study was designed to assess the safety and availability of multiple 10mg/kg intravenous doses of the drug, the highest dose expected to be used in its planned phase II clinical study.
Adalta chief executive officer Dr Tim Oldham said "the data being generated continues to show that AD-214 is well-tolerated and is also helping to inform dosing regimens and the broader protocol for our coming phase II study for AD-214".
"It is additive to our recent laboratory studies which indicated that commercially suitable dosing frequencies could be clinically effective," Dr Oldham said. "In parallel with these workstreams, we have been progressing partnering and project financing discussions to help secure the funds to progress AD-214 into phase II studies."
Adalta said it expected to have pharmaco-kinetic and receptor engagement results from the first three doses available for discussion with partners in November 2023, with full safety and tolerability results expected by April 2024.
Adalta fell 0.2 cents or 9.1 percent to two cents.

CANN GROUP

Cann Group says Melbourne's Levin Health Pty Ltd has agreed to buy about $1.58 million of additional marijuana flower products from by December 31, 2023.
In June, Cann said it had an $880,000 agreement with Levin Health to supply its medical cannabis dried flower and oils from July 1 to December 31, 2023 (BD: Jun 20, 2023).
Today, the company said Levin made the additional purchase order of marijuana flower products to meet its production schedule, bringing the total order to $2.29 million.
Cann said it would also supply $850,000 of its marijuana oil products to Levin under the agreement to December 31, 2023.
Cann chief executive officer Peter Koetsier said that "securing longer-term supply agreements with our preferred partners" was critical for the Cann Group strategy.
Cann was up 0.25 cents or 2.1 percent to 12.25 cents.

BOTANIX PHARMACEUTICALS

Botanix has told the ASX that it is not aware of any information it has not announced, which, if known, could explain recent trading in its securities.
The ASX said the company's share price rose 23.5 percent from a 17.0 cent closing price on September 14, 2023 to an intra-day high of 21.0 cents on September 19, nothing a "significant increase" in trading volume.
Botanix told the ASX it was awaiting a US Food and Administration decision on its sofpironium bromide for hyperhidrosis, or excess sweating, which it expected "in late September 2023" and a positive decision would be "a significant milestone … [paving] the way for an expansion of the company's operations and revenue generation".
Botanix said it considered that "speculation as to the anticipated FDA decision could potentially explain the recent trading in its securities".
Botanix fell half a cent or 2.5 percent to 19.5 cents with 5.2 million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics has requested an extension to its suspension pending an announcement regarding “the application for regulatory approval of the Promarkerd test”.
On Monday, Proteomics requested a suspension following a trading halt the previous week (BD: Sep 14, 18, 2023).
Trading will resume on September 25, 2023, or on an earlier announcement.
Proteomics last traded at 90 cents.

STARPHARMA HOLDINGS

FIL (Fidelity Investment Management Ltd) says it has reduced its substantial shareholding in Starpharma from 25,777,420 shares (6.28%) to 21,422,025 shares (5.22%).
The Hong Kong-based Fidelity said that between August 16 and September 18, 2023 it sold 4,355,395 shares at prices ranging from 15.00 cents to 16.95 cents.
Starpharma fell 1.5 cents or 8.8 percent to 15.5 cents.

ACTINOGEN MEDICAL

The San-Francisco and Cayman Islands-based BVF Partners says its 247,334,680 share-holding in Actinogen has been diluted from 13.77 percent to 12.35 percent.
Earlier this month, Actinogen said its one-for-4.54 non-renounceable rights issue at 2.5 cents a share raised $10,001,449, with $4,645,076 in subscriptions and $5,356,373 in shortfall commitments (BD: Sep 7, 2023).
Actinogen was unchanged at 1.8 cents with 6.9 million shares traded.

RECCE PHARMACEUTICALS

FIL (Fidelity Investment Management Ltd) says it has become a substantial shareholder in Recce with 15,144,466 shares, or 7.69 percent.
The Hong Kong-based Fidelity said that on September 18, 2023 it bought 8,191,153 shares at 44.0 cents a share.
Last week, Recce said it had raised $8 million in a placement at 44 cents a share and hoped to raise a further $3 million in a rights offer (BD: Sep 11, 2023).
Recce fell two cents or 4.1 percent to 46.5 cents.