Biotech Daily

Monday June 7, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: UNIVERSAL BIOSENSORS UP 7%; IMUGENE DOWN 5%**

*** TRAJAN CLIMBS 20% ON $90m IPO**

*** EMYRIA: 'MARIJUANA REDUCES OPIOID USE, SIGNIFICANTLY'**

*** TELIX, ATS $1.6m EUROSTARS ANTI-CANCER ALPHA GRANT**

*** IMMUTEP: 'ENCOURAGING' INSIGHT-004 IMP321 COMBO TUMOR DATA**

*** IMMUTEP: 'POSITIVE' TACTI-002 IMP321, KEYTRUDA CANCER DATA**

*** DIMERIX: UK INNOVATION PASSPORT, ILAP STATUS FOR DMX-200**

*** CLINUVEL DOSES 1st AFAMELANOTIDE STROKE PATIENT**

*** KAZIA ENROLS 1st PHASE II PAXALISIB LYMPHOMA PATIENT**

*** UNIVERSAL BIOSENSORS 1st EUROPEAN SENTIA WINE TEST SALES**

*** AZURE APPOINTS ALTIPURE MANUFACTURER**

*** HELEN FOURAS, VELOCIMETRY 'REDUCE', DILUTED TO 43% IN 4D**

*** 4D FOUNDER, CEO PROF ANDREAS FOURAS DILUTED TO 22%**

*** TBG SELLS 5% OF TBG INC TO BEIJING'S DONG YUAN FOR $1.1m**

*** TALI: DETECT HAS 20k INDIA DOWNLOADS**

*** PYC REQUESTS 'PRE-CLINICAL RESULTS' TRADING HALT**

*** VERITAS BELOW 5% IN COCHLEAR**

*** TRAJAN APPOINTS MARK LICCIARDO JOINT CO-SEC**

*** MACH7 APPOINTS DAVID MADAFFRI HEAD OF SALES**

MARKET REPORT

The Australian stock market fell 0.19 percent on Monday June 7, 2021, with the ASX200 down 13.5 points to 7,281.9 points. Nine of the Biotech Daily Top 40 stocks were up, 23 fell and eight traded unchanged. All three Big Caps were up.

Universal Biosensors was the best, up 4.5 cents or 7.3 percent to 66 cents, with 411,605 shares traded. Patrys climbed 7.1 percent; Actinogen and Optiscan both improved 6.9 percent; Neuren was up 3.2 percent; Amplia, Cyclopharm and Dimerix rose more than two percent; with Cochlear, CSL, Pro Medicus and Resmed up by less than one percent.

Imugene led the falls, easing two cents or 5.1 percent to 37 cents, with 17.65 million shares traded. Impedimed, LBT, Mesoblast, Oncosil and Proteomics fell more than four percent; Starpharma and Volpara were down more than three percent; Antisense, Clinuvel, Medical Developments, Paradigm, Polynovo and Prescient shed more than two percent; Genetic Signatures, Immutep, Kazia, Next Science, Nova Eye and Opthea were down more than one percent; with Avita, Cynata and Telix down by less than one percent.

TRAJAN MEDICAL AND SCIENTIFIC

Trajan opened up 16 cents or 9.4 percent at $1.86 following its $90 million initial public offer at $1.70 on its and climbed as much as 34 cents or 20 percent to $2.04.
In May, Trajan founder and chief executive officer Stephen Tomisich told Biotech Daily the funds would be used “for the next suite of acquisition targets” (BD: May 11, 2021).
Mr Tomisich said the company began with liquid chromatography and mass spectrometry, for precision workflow for a range of industries from food to biotechnology.
Last week, Trajan said it was a “developer and manufacturer of analytical science instruments, devices, and solutions used in biological, food and environmental analysis”, with products used across the analytical workflow and had broad life science applications including pharmaceutical, clinical diagnostics and pathology (BD: Jun 2, 2021).
Trajan closed up 28 cents or 16.5 percent at $1.98 with 5.3 million shares traded.

EMYRIA

Emyria says that its personalized marijuana plans reduce opioid use among high opioid use patients by up to 34.2 percent ($p < 0.0001$).
Emyria chief executive officer Dr Michael Winlo said the study followed 474 patients for 12 months before and after treatment, and found the group taking more than 90mg of morphine equivalent per day and treated with combinations of tetrahydrocannabinol (THC) and cannabidiol (CBD) showed the greatest decrease in opioid use.
A chart presentation posted by the company showed that among “moderate” opioid users, those taking 40mg to 90mg per day, there was a decline of 33.1 percent in opioid use at six months ($p = 0.01$) and “low” dose users had a non-significant 25 percent reduction.
Dr Winlo said that 90 percent of the patients were taking opioids for chronic pain.
Dr Winlo said that the opioid use patient data was collected by Melbourne’s Nostradata and compared with patients on its treatment plans.
The Emyria presentation showed that high and moderate dose patients taking cannabinoids for less than six months retained a decline in opioid use over 12 months.
In April, the Australian Medical Association said that a 100-patient trial at Melbourne’s Austin Hospital showed that 400mg cannabidiol had no significant difference to placebo for acute low back pain among patients taking oxycodone (BD: Apr 20, 2021).
The research, published in the Medical Journal of Australia, said that 5mg oxycodone every six hours was administered after 120 minutes if pain was not adequately managed, and the emergency department doctor could administer rescue oxycodone at any time.
Emyria was up half a cent or 2.4 percent to 21.5 cents with 1.1 million shares traded.

TELIX PHARMACEUTICALS

Telix says the Eureka Association has provided a EUR990,000 ($A1.56 million) ‘Eurostars-2’ research grant to it and Alpha Therapy Solutions.
Telix said its European subsidiary Advanced Nuclear Medicine Ingredients SA and the Gothenburg, Sweden-based Alpha Therapy received the grant from the international Eureka Association to develop a new anti-cancer targeted alpha therapy using the alpha-particle emitting radioisotope, astatine-211.
Telix chief scientist Dr Michael Wheatcroft said that “coupling the tumor-targeting specificity of peptides and antibodies with the cell-killing power of alpha-emitting radioisotopes offers potential in creating more effective therapeutics in certain cancers.”
Telix fell four cents or 0.9 percent to $4.63 with 272,932 shares traded.

IMMUTEP

Immutep says it has “encouraging” final data from its 12-patient, phase I, Insight-004 combination trial of IMP321 and avelumab in different solid tumors.

Immutep said the trial, in collaboration with the Darmstadt Germany-based Merck KGgA, had no complete responses but said that five of 12 patients (41.7%) had an “objective response” which showed “encouraging early activity signals” and all five patients had reported a partial response to the combination therapy of eftilagimod alpha (IMP321) with the anti-programmed cell death ligand-1 (PD-L1) antibody avelumab (Bavencio).

Last year, the company said the six-patient second cohort received a standard dose of avelumab and six milligrams of IMP321, with no new safety signals or dose limiting toxicities (BD: Apr 22, 2020).

Today, Immutep said the combination treatment was well tolerated with no dose limiting toxicities.

The company said disease control was seen in six of the 12 patients and nine of the 12 patients (75%) were still alive.

Immutep said “the final efficacy and safety data … is promising and warrants further clinical evaluation of this new combination … with distinct tumor indications”.

Immutep chief scientific officer Dr Frederic Triebel said that the “final results of the Insight-004 study show promising activity signals from efti in combination with avelumab in a variety of solid cancers, primarily gastrointestinal”.

“Importantly it continues to be well-tolerated,” Dr Triebel said.

Immutep fell one cent or 1.5 percent to 65.5 cents with six million shares traded.

IMMUTEP

Immutep says it has “positive” interim data from its up-to 183-patient study of IMP321 with Keytruda in non-small cell lung cancer and head and neck squamous cell carcinoma.

Immutep said the Tacti-002, phase II trial of IMP321, or eftilagimod alpha, and pembrolizumab (Keytruda) showed that 15 patients out of 36 with non-small cell lung cancer (NSCLC) had a “favorable” overall response, with two complete responses and 13 partial responses, and the minimum duration of response was more than six months.

The company said the combination therapy of eftilagimod alpha and pembrolizumab for head and neck squamous cell carcinoma (HNSCC) showed 11 patients out of 37 with an overall response, of which five patients had a complete response and six had a partial response, with the minimum duration of response more than six months.

Immutep said chief scientific officer Dr Frederic Treibel said that the company was “seeing nearly 50 percent of the evaluable first line [non-small cell lung cancer] patients responding to the therapy, as scored by a blinded, independent, central review committee, with responses in all PD-L1 sub-groups and a favorable median [progression free survival]”.

“Overall, the NSCLC patients receiving this first line therapy are living 8.2 months without their disease progressing, a promising improvement for a chemo-free first line regimen,” Dr Treibel said.

“In effect, we are seeing an improvement in patient outcomes compared with that historically seen with anti-PD-1 monotherapy but with a similar safety profile and, also, comparable results in terms of [objective response rate] and [progression free survival] to chemo positive anti-PD-1 combination therapy but, importantly, with a longer duration of response and lower toxicity,” Dr Treibel said.

DIMERIX

Dimerix says DMX-200 has been awarded an Innovation Passport and Innovative Licensing and Access Pathway designation for focal segment glomerulo-sclerosis.
Dimerix said the UK Medicines and Healthcare products Regulatory Agency (MHRA) awarded the ILAP designation “to accelerate development and access to promising medicines” such as DMX-200 following a review of its clinical data that showed that patients were likely to benefit from the product.
The company said the Innovation Passport provided entry into the Innovative Licensing and Access Pathway which supported “innovative approaches to the safe, timely and efficient development of medicines to improve patient access”.
Dimerix managing-director Dr Nina Webster said that the “granting of the Innovation Passport and entry into ILAP comes in addition to the orphan drug designation we already have granted in both [the] US and Europe”.
“These designations ultimately accelerate the review of promising therapies targeting unmet medical needs,” Dr Webster said.
Dimerix was up half a cent or 2.1 percent to 24.5 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says it has dosed the first of six patients with afamelanotide in the phase II CUV801 trial for acute arterial ischaemic stroke.
Clinuvel said the study would focus on the safety and therapeutic potential of afamelanotide in patients who are ineligible for standard stroke therapy.
The company said the patients would be assessed to detect changes or improvement in neurological functions and activities of daily living.
Clinuvel said it would monitor changes by assessing the periodic magnetic resonance imaging (MRI) brain scans, the blood volume and flow to the affected regions of the brain, with a special attention to the core of the stroke (infarct) and penumbra.
In March, the company said it would expand is study of Scenesse, 16mg afamelanotide, for DNA repair in xeroderma pigmentosa (BD: Mar 24, 2021).
Today, Clinuvel said afamelanotide was known to offer neuro-protection, act as a potent anti-oxidative hormone, activate vessels, reduce fluid formation, protect critical nerve, and brain tissue, and restore the blood brain barrier.
The company said the drug therapy was expected to affect the blood flow and oxygen to deprived brain tissue.
Clinuvel clinical operations manager Dr Pilar Bilbao said that the “immediate aim … is to bring back the patient’s neurological and muscular functions by improving the blood flow to the affected site of the brain”.
Clinuvel fell 82 cents or 2.85 percent to $27.95 with 54,271 shares traded.

KAZIA THERAPEUTICS

Kazia says it has enrolled the first of up-to 25-patients in its phase II study of paxalisib in primary central nervous system lymphoma at Dana-Farber Cancer Institute.
Kazia said the open-label phase II trial at Boston’s Dana-Farber Institute was expected to be completed within two years and the company would provide support which included the study drug and a financial grant.
The company said that the primary endpoint would be overall response rate, measured by the growth or shrinkage of tumor on a brain scan during and after treatment.
Kazia fell two cents or 1.6 percent to $1.25.

UNIVERSAL BIOSENSORS

Universal Biosensors says it has had its first sales of its Sentia device and test strips to companies operating in France, Italy, Germany, Spain, Portugal and Switzerland.
Universal Biosensors said Vinventions SA would sell the devices and strips in France and Italy, with AZ3Oeno SL Enologia Viva distributing the test and strips in Spain and Portugal.
The company said that with XC Oenologie Sàrl had been appointed its Switzerland distributor on a three-year term with agreed initial purchase volumes.
Universal Biosensors chief executive officer John Sharman said that "the launch of Sentia into the main European markets is a significant step forward for the company".
"Between Vinventions, AZ3Oeno and XC Oenologie Sàrl, we have access to more than 26,000 wineries across Europe," Mr Sharman said.
"Our business is forecasting to hit $1 million of sales before the end of September," Mr Sharman said.
Universal Biosensors was up 4.5 cents or 7.3 percent to 66 cents.

AZURE HEALTH TECHNOLOGY (MERGED WITH INVICTUS, TRADING AS VGI)

Azure says it has appointed Altipure LLC as an additional good manufacturing practice manufacturer after producing drugs for two phase II clinical studies.
Azure said that the pilot manufacturing run manufactured 60,000 doses of active clinical study drug, expected to arrive in Australia in July 2021.
Azure chief executive officer Dr Glenn Tong told Biotech Daily that the Alexandria, Ohio-based Altipure was the manufacturing partner for the Nashport, Ohio-based Muscle Feast LLC which was contracted by Azure.
The company said that half of the doses were IVB001 for a non-alcoholic fatty liver disease or non-alcoholic steato-heptatitis phase II study and the other half were IVB003 for the pancreatic cancer phase II study.
Azure said that IVB001 and IVB003 were tocotrienols using the company's trans-mucosal delivery platform.
The company said that Altipure had validated and optimized the manufacturing for its food additives NE1-Elite for delayed onset muscle soreness and muscle recovery and NE1-Heart for heart health.
Azure was untraded at 22 cents.

4D MEDICAL

Velocimetry Consulting Pty Ltd and Helen Fouras say they have reduced and been diluted in 4D Medical from 134,541,408 shares (50.82%) to 127,290,329 shares (43.23%).
Ms Fouras' husband and 4D chief executive officer Prof Andreas Fouras told Biotech Daily that the change was due to the release of shares relating to pre-initial public offer convertible notes and the consequential shares and escrow arrangements.
Prof Fouras said that neither Velocimetry nor Ms Fouras had sold shares but were considered related parties due to the ASX escrow arrangements.
Velocimetry and Ms Fouras said they were diluted following the recent placement and share plan that raised $46 million at $1.55 (BD: Apr 1, 2021).
In a separate substantial shareholder notice signed by company secretary Charlene Stahr, 4D Medical said it had reduced and been diluted from 134,541,408 shares (50.82%) to 127,290,329 shares (43.23%).
4D fell three cents or 2.3 percent to $1.27.

4D MEDICAL

Founder and chief executive officer Prof Andreas Fouras says his 64,838,000 share-holding in 4D has been diluted from 24.49 percent to 22.02 percent (see above).

TBG DIAGNOSTICS

TBG says it will sell about five percent of subsidiary TBG Inc to the Beijing-based Dong Yuan Hua Xin Capital Management for RMB5,500,000 ($A1,095,000) or 13.6 cents a share.
TBG said that following the sale, it would hold 41.25 percent of TBG Inc while Dong Yuan would hold 38.71 percent of its shareholding.
The company said that TBG Inc owned 100 percent of TBG Biotechnology Xiamen Inc.
TBG said the sale would be completed within 10 business days after Dong Yuan obtains necessary approvals and if it fails to do so by September 30, 2021 the company had the right to terminate the agreement without further liability.
TBG has been suspended since last year and last traded at 27 cents (BD: Mar 19, 2021).

TALI DIGITAL

Tali says the more than 20,000 downloads for Detect from the India Google Play Store, “exceeding expected activity levels”.
In April, Tali said its partnership with the Times Group of India for its cognitive performance tools Tali Detect and Tali Train had begun ahead of schedule and its direct-to-consumer versions of the products for children with attention and learning difficulties aged three to eight years were available on India’s Google Play Store (BD: Apr 12, 2021).
Today, the company said it had significant numbers of positive customer reviews rating it a 4.5-star (of 5) which indicated that the product was well received and product localization had been successful.
Tali said the ‘live-launch’ of its applications and complete roll-out of the print and radio campaigns were scheduled for later in 2021.
Tali fell one cent or 2.9 percent to 3.4 cents with 1.4 million shares traded.

PYC THERAPEUTICS

PYC has requested a trading halt pending an announcement regarding preclinical results of the effectiveness of its drug candidate for autosomal dominant optic atrophy.
Trading will resume on June 9, 2021 or on an earlier announcement.
PYC last traded at 18.5 cents.

COCHLEAR

Veritas Asset Management it has ceased its substantial shareholding in Cochlear from 3,291,498 shares (5.01%) to 2,788,198 shares (4.241%).
The London-based Veritas Asset Management said that on May 28 and June 4, 2021 it sold 503,300 shares for $115,692,722 or $230.00 a share.
Cochlear was up $1.35 or 0.6 percent to $230.20 with 108,483 shares traded.

TRAJAN GROUP HOLDINGS

Trajan says it has appointed Mark Licciardo of Mertons Corporate Services as joint company secretary, effective from June 4, 2021.
Trajan said its chief financial officer Alister Hodges would remain a joint company secretary.

MACH7 TECHNOLOGIES

Mach7 says it has appointed David Madaffri as its head of sales.
Mach7 said that Mr Madaffri had worked Philips Healthcare for 12 years in sales and was most recently its head of sales for enterprise diagnostic informatics for North America.
According to his Linkedin page, Mr Madaffri holds an Associate Degree in Radiologic Technology from the Beaumont, Texas-based Lamar University and a Bachelor of Science in business and management from the St Louis, Missouri Webster University.
Mach7 fell half a cent or 0.5 percent to $1.075.