Biotech Daily

Wednesday September 28, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: DIMERIX UP 15%; TELIX DOWN 15%**

*** TELIX WITHDRAWS ILLUCCIX EU APPLICATION ON DATA REQUEST**

*** TELIX: CHINA OKAYS PHASE III TLX250-CDX KIDNEY CANCER TRIAL**

*** OSTEOPORE PRODUCTS ADDED TO TGA PROSTHESES LIST**

*** OSTEOPORE: CHILE $353k FOR BONE REGENERATION IMPLANT**

*** RACE DEVELOPS PERIPHERAL I-V ZANTRENE FORMULATION**

*** EXOPHARM: NO IMMUNOGENICITY, TOXICITY OF EXOSOMES, IN MICE**

*** TISSUE REPAIR: FDA 'ACCEPTS' TR-987 WOUND CARE PROTOCOL**

*** RESPIRI OPENS PHILIPPINE DIGITAL INNOVATION CENTRE**

*** COGSTATE PLEADS SCHULTZ, EISAI TO ASX 61% QUERY**

*** TGA FINES 3 'MEDICAL MARIJUANA' COMPANIES $972K**

*** CRONOS NOTICE TO ELECT DR BENJAMIN JANSEN DIRECTOR**

*** MEDLAB RECEIVES 'MDLB' NASDAQ CODE**

*** DIRECTOR PAUL LEWIS, INVIA INCREASE, DILUTED TO 6.45% IN HYDRIX**

*** ROGER ALLEN DILUTED TO BELOW 5% IN HYDRIX**

*** MAYNE APPOINTS SHAWN O'BRIEN CEO, ON $938k PA**

*** IDT: MARK LICCIARDO CO SEC, MAHENDRAN VASANTHAKUMAR CFO**

*** DR MICHAEL AUSTIN REPLACES TISSUE REPAIR CO SEC ALISTAIR MCKEOUGH**

MARKET REPORT

The Australian stock market fell 0.53 percent on Wednesday September 28, 2022, with the ASX200 down 34.2 points to 6,462.0 points. Twelve of the Biotech Daily Top 40 companies were up, 19 fell, eight traded unchanged and one was untraded.

Dimerix was the best, up two cents or 15.4 percent to 15 cents, with 241,038 shares traded. Universal Biosensors and Volpara climbed more than eight percent; Avita and Cynata were up four percent or more; Clinuvel and Impedimed improved more than three percent; Orthocell rose 2.5 percent; Cyclopharm, Pharmaxis and Polynovo were up more than one percent; with Antisense, Cochlear and Resmed up by less than one percent.

Telix led the falls, down 83 cents or 15.4 percent to $4.56, with 4.5 million shares traded. Emvision lost 9.9 percent; Imugene and Prescient were down more than five percent; Alcidion, Genetic Signatures, Neuren, Oncosil and Starpharma fell four percent or more; Next Science and Proteomics lost three percent or more; Actinogen, Micro-X and Paradigm shed more than two percent; Atomo and Nanosonics were down more than one percent; with CSL, Medical Developments, Mesoblast and Pro Medicus down by less than one percent.

TELIX PHARMACEUTICALS

Telix says it has withdrawn its European marketing authorization application for its Illuccix for prostate cancer imaging.

Telix said that Illuccix, or gallium-68-gozetotide-prostate specific membrane antigen-11 (68Ga PSMA-11) was approved by the US Food and Drug Administration and the Australian Therapeutic Goods Administration.

The company said that "in the late stages of review, the Danish Medicines Agency, in consultation with other European regulatory authorities, has requested additional chemistry, manufacturing and control data … [which could] not be reasonably delivered within the prescribed review timeframe".

In 2020, Telix said it had filed the application to the Danish regulator (BD: May 1, 2020).

Today, the company said the request was "an unexpected and extremely disappointing result considering that Illuccix has been approved by other major global regulators and given the company's track record of delivering PSMA [positron emission tomography] imaging reliably and safely to tens of thousands of European men with prostate cancer under compassionate and 'magisterial' use availability".

"Ultimately, this is a poor outcome for patients," Telix said.

Telix managing-director Dr Christian Behrenbruch said: "This is not the outcome we expected, despite our best efforts to meet all regulator information requests."

"The outcome is reflective of the novelty of our submission approach … and the specific nuances of European product approval requirements," Dr Behrenbruch said.

"We are confident that the additional data can be provided, but the prescribed timeframes of the review process mean that the most efficient process is to withdraw the application and then resubmit," Dr Behrenbruch said. "We remain committed to bringing an approved 68Ga-PSMA-11 product to market in Europe."

Telix said it intended to resubmit for a marketing authorization for Illuccix in Europe.

The company said it was assessing alternative regulatory options with a revised submission including pathways not available at the time of the original filing.

Telix fell 83 cents or 15.4 percent to $4.56 with 4.5 million shares traded.

TELIX PHARMACEUTICALS

Telix says the Chinese National Medical Products Administration has approved its phase III study of TLX250-CDx (89-zirconium-girentuximab) for kidney cancer.

In July, Telix said it had dosed the last of 300 patients in the Zircon phase III TLX250-CDX for imaging kidney cancer trial, with results expected this year (BD: Jul 11, 2022).

Today, Telix said the study would "bridge to Telix's global phase III Zircon trial of TLX250-CDX for the imaging of clear cell renal cell carcinoma with positron emission tomography".

Telix said that the study was required to provide supplementary data obtained in a Chinese population to establish the diagnostic efficacy of the product was equivalent in Chinese and Western populations.

The company said that a "dosimetry study enrolling 10 patients" would precede the multi-centre phase III bridging study, expected to enrol 100 patients, which combined with the Zircon trial results could "support a future marketing authorization application for TLX250-CDx in China.

Telix Asia Pacific chief executive officer for Dr David Cade said the approval of its investigational new drug application was "a significant milestone for Telix and our partner Grand Pharma, enabling us to proceed with a pivotal registration study and ultimately bring new options to the 73,000 people newly diagnosed with renal cell carcinoma in China each year where there is currently critical unmet medical need".

OSTEOPORE

Osteopore says that all of its products currently on the Australia Register of Therapeutics Goods will be included in the Prostheses List on November 25, 2022.

Osteopore said that the Australia Protheses List identified implantable devices which were eligible for reimbursement from all private health insurance funds and allowed doctors and surgeons to choose “the best available prostheses for privately insured patients as covered by all the individual healthcare insurance funds”.

The company said that its products underwent “a rigorous application and review process to be incorporated onto the list” that was expected to “remove barriers to the recommendation of our products to suitable patients in the future, as the implants could potentially reduce the overall healthcare costs of patients”.

Osteopore was unchanged at 22 cents.

OSTEOPORE

Osteopore says it has a $US225,000 ($A352,708) grant from the Chile Government to develop a three-dimensional printable implant to accelerate bone regeneration.

Osteopore said its current implant enabled the natural stages of bone healing and were “superior to other traditional bone regeneration procedures” but by “incorporating materials and compounds that speed up bone growth, a patients’ recovery could be accelerated”.

The company said that research would begin in October 2022 with the University of Chile, which would provide non-incremental expenses of $US135,000 towards the project.

Osteopore said it was yet to discuss certain terms in relation to the research it would undertake with the University of Chile.

Osteopore chair Mark Leong said the company was “extremely excited about this partnership, as it comes with non-dilutive funding and could see enormous potential commercial opportunities if successful”.

“Developing materials that can speed up bone regeneration would have far-reaching positive clinical outcomes for patents globally, and we continue to see scientists and clinicians around the world take an interest in the Osteopore technology,” Mr Leong said.

“We will continue to collaborate with industry stakeholders to improve our technology and develop new applications that improve patient care now and in the future,” Mr Leong said

RACE ONCOLOGY

Race says it has developed a new formulation of Zantrene, RC220, that enables peripheral arm or leg intra-venous delivery to patients for cancer treatment.

Race said that previously, Zantrene required the use of an invasive central venous catheter, that could only be performed in a hospital setting, and was “not optimal for patients with solid tumors” where peripheral, arm or leg vein, intra-venous infusion in an outpatient setting was preferred.

The company said that there were a number of benefits to the peripheral intra-venous delivery of Zantrene, including less pain and lifestyle disruptions, it made dosing easier and more accurate, lessened requirements on skilled healthcare personnel, and could deliver Zantrene more rapidly to the patient.

Race said that it would produce the RC220 formulation to current US Food and Drug Administration current good manufacturing practice standards with the San Diego, California-based Societal, expected to be delivered by late December 2023, and expected to cost $US611,900 ($A955,611).

Race was up eight cents or 4.2 percent to $2.00.

EXOPHARM

Exopharm says preliminary results of its toxicology study did not detect immunogenicity or toxicity of its manufactured exosomes, in mice.
Exopharm said that exosomes as a drug-delivery vehicle could be seen by a patient's immune system as "harmless" meaning they could be dosed many times.
The company said that the study dosed mice intra-venously over 23 days, with a total of 10 doses per mice and interim results showed that repeated dosing "was safe and did not generate an immune response despite up to 10 doses of around 3.4 billion particles per dose over 23 days", indicating that the exosome carrier was "silent to the recipient's immune system and non-toxic".
Exopharm chief executive officer Dr Ian Dixon said "the exosomes tested in this pivotal immunogenicity and toxicology study showcase the significant progress we have made over the past 24 months."
"These exosomes come from our highly-scalable … HEK293 cells, which were produced and collected in our improved cell culture system and purified using our latest protocols of the patented Leap purification step," Dr Dixon said.
Exopharm was unchanged at 14 cents.

TISSUE REPAIR

Tissue Repair says the US Food and Drug Administration has "broadly accepted" its TR-987 phase III program for chronic wounds, but declined fast track status.
Tissue Repair said that the FDA had "broadly accepted as reasonable" its intended approach to chemistry manufacturing and controls, raw materials and toxicology.
The company said it sought advice on fast-track designation and/or breakthrough therapy designation but the FDA could not accept them based on its phase IIb study alone.
Tissue Repair said the FDA noted that if it conducted a further phase II trial, it might only have to conduct a single, phase III trial, rather than two, and if it could show that TR-987 had the potential to address venous stasis ulcers then it could formally submit either fast track or breakthrough therapy designation applications.
Tissue Repair said that it expected to begin its phase III trials in 2023 and the adjusted work program required by the FDA could be funded from its existing cash reserves.
Tissue Repair fell half a cent or 1.6 percent to 30 cents.

RESPIRI

Respiri says it has established a Philippine-based 'centre of digital innovation excellence' for growth, market flexibility, cost reduction and increased productivity.
Respiri said the centre was estimated to reduce information technology costs by about $700,000 a year, and increase productivity by 30 percent, as well as centralizing resources into one time zone for "a more collaborative work environment".
The company said the centre would improve all aspects of its research and development, allow access to Filipino software engineering resources and allow it to partner with technology vendors and service provides to reduce costs and improve productivity.
Respiri said the centre would design and develop software for its digital products and technology and ensure all intellectual property was maintained within the company.
Respiri chief executive officer Marjan Mikel said the centre of excellence would "accelerate our digital design and development capabilities and allow further improvements in productivity and efficiency through its low-cost location".
Respiri fell 0.1 cents or 2.3 percent to 4.2 cents.

COGSTATE

Cogstate 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 61.4 percent from $1.40 at the close of trading on September 27, to a high of $2.26 today, but did not note an increase in the trading volume.

Cogstate said that earlier today, Tokyo's Eisai Co announced that its 1,795-patient, confirmatory, phase III Clarity study of Lecanemab for Alzheimer's disease met the primary endpoint, showing a statistically significant reduction of clinical decline in patients with early Alzheimer's disease.

The company said that it was not a party to the Eisai and Biogen Inc agreement and did not have access to, nor was otherwise aware of, any information in relation to this development other than as publicly released by Eisai and Biogen.

Cogstate said that in 2020 it granted Eisai exclusively rights to develop and distribute its digital cognitive assessment technologies in healthcare and other markets worldwide, but specifically excluded the clinical trials market, in which Cogstate marketed its products independently (BD: Oct 26, 2020).

The company said that "save for the announcement by Eisai and Biogen earlier today, which has been reported in the Reuters article referred to in the ASX Letter, the company is not aware of any other explanation for the recent trading in its securities".

Cogstate closed up 50.5 cents or 36.1 percent to $1.905.

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION

The Australian Therapeutic Goods Administration says it has fined Cannatrek, Little Green Pharma and MGC Pharmaceuticals a total of $972,360 over advertising.

The TGA said the 73 infringement notices related to "alleged unlawful advertising", with Little Green Pharma receiving 28 notices for a total of $372,960 in fines, MGC Pharmaceuticals receiving 23 notices for $306,360 in fines and Cannatrek 22 notices for $293,040 in fines.

The Administration said the fines were for "the alleged unlawful advertising of medicinal cannabis products on their websites and social media platforms".

The TGA said that the companies "allegedly promoted the use of prescription-only medicinal cannabis products, including in certain cases their own named products, that are unapproved medicines, that is, not entered on the Australian Register of Therapeutic Goods.

"It is also alleged that the unlawful advertising included unapproved references to the treatment of serious diseases or conditions, including in some cases cancer and epilepsy," the TGA said. "Further, some advertising allegedly suggested or implied that particular medicinal cannabis products were recommended or approved by a government authority."

Biotech Daily no longer covers Little Green Pharma or MGC, which are reported in our sister publication Ag & Vet Weekly, along with the public unlisted Cannatrek.

MEDLAB CLINICAL

Medlab says it has filed applications to three US bodies to list on the Nasdaq and has received the reserved symbol MDLB.

Medlab said that once it listed on the Nasdaq, it would be dual listed with the ASX.

Medlab fell 38 cents or 3.3 percent to $11.02.

CRONOS AUSTRALIA

Cronos says it has received a notice under Section 249N of the Corporations Act 2001 to appoint Dr Benjamin David Ngahuia Jansen as a director.
Cronos said the notice came from Elizabeth Sarah Jansen as trustee for the Stanford Investment Trust.
The company said the notice of annual general meeting was expected to be made available to shareholders by mid to late October 2022.
Last week, Cronos said it had received a section 249D notice calling for the removal of two directors, from Matua Hasyo Charlie Jansen as trustee for the Whanau Family Trust (BD: Sep 20, 2022).
The company told Biotech Daily at that time that Dr Matua Jansen was a founder of Cannabis Doctors Australia, which it acquired in 2021, and a former doctor with Cannabis Doctors Australia (BD: Sep 14, Dec 16, 2021).
Cronos said the resolutions called for the removal of director and chief executive officer Rodney Cocks and director and chief commercial officer Guy Headley at its next annual general meeting.
On Friday, Cronos said that chief medical officer and director Dr Benjamin D N Jansen "ceased his position" effective from September 22, 2022 (BD: Sep 23, 2022).
Cronos said Dr Benjamin Jansen was also a founding director of Cannabis Doctors Australia.
Dr Jansen's Appendix 3Z final director's notice said that he held directly 333,333 shares, as well as 130,223,903 shares held indirectly, through Elizabeth Sarah Jansen as trustee for Stanford Investment Trust, and Biotech Daily calculates Dr Jansen holds 23.55 percent of Cronos.
Last week, the company said it would hold its annual general meeting on November 29, 2022, and nominations for directors must be received by September 28, 2022.
Last December, Dr Matua Jansen said that he became a substantial shareholder with 55,413,425 Cronos shares or 10.10 percent of the company.
Cronos was up 5.5 cents or 8.8 percent to 68 cents.

HYDRIX

Director Paul Lewis AND Invia Custodian Pty Ltd says he has increased and been diluted in Hydrix from 9,916,666 shares (5.02%) to 14,875,000 shares (6.45%).
The Sydney-based Mr Lewis said that on September 23 he subscribed for 4,958,334 for $297,500 or six cents a share and was diluted in the entitlement offer.
Earlier this month, Hydrix said it had raised about $2.07 million in the "fully subscribed" institutional component of its one-for-two, non-renounceable entitlement offer at six cents a share, and that it hoped to raise a further about $3.93 million in its retail component (BD: Sep 15, 19, 2022).
Hydrix was up 0.2 cents or 3.5 percent to 5.9 cents.

HYDRIX

Sydney's Roger Allen says he has ceased his substantial holding in Hydrix following the issue of rights offer shares on September 23, 2022 (see above).
In March, Mr Allen said that through Patagorang Pty Ltd he had become substantial in Hydrix, with 10,452,380 shares, or 5.45 percent of the company (BD: Mar 31, 2022).

MAYNE PHARMA

Mayne says it has appointed Shawn Patrick O'Brien as its chief executive officer and managing-director on $US600,000 ($A938,476) a year, effective from October 1, 2022.
Mayne said Mr O'Brien had more than 35 years of pharmaceutical industry experience, was a founding partner of Key Biopharma Partners and had previously worked for Genomind Inc as chief executive officer and chair, Cipher Pharmaceuticals Inc, Altherx Pharmaceuticals, Profectus Biosceinces and Solstice Neurosciences as chief executive officer, as well as Astrazeneca in a number of roles.
The company said that Mr O'Brien held a Bachelor of Science from the University of Western Ontario.
Mayne said that Mr O'Brien would receive a yearly salary of $US600,000, short term incentives of up to 50 percent of his salary, and a further 150 percent of his salary in long term incentives, subject to performance hurdles.
Mayne was up one cent or 3.9 percent to 26.5 cents with 7.2 million shares traded.

IDT AUSTRALIA

IDT says it has appointed Mark Licciardo as company secretary and Mahendran Vasanthakumar as acting chief financial officer.
IDT said that Mr Licciardo's appointment would be effective from October 3, 2022, and that he currently worked at Acclime Corporate Services Australia Pty Ltd.
The company said that Mr Licciardo was the founder of Mertons Corporate Services, now part of Acclime and he currently was a director of a number of companies.
According to his Linkedin page, Mr Licciardo held a Bachelor of Accounting and a Bachelor of Business from Melbourne's Victoria University.
IDT said that Mr Vasanthakumar's appointment was effective from today, and that he had more than 40 years of experience in pharmaceutical and fast-moving consumer goods industries, most recently working for Pfizer Australia Pty Ltd as head of finance.
IDT said that Mr Vasanthakumar had previously worked for Hospira, Mayne Pharma and Faulding Pharmaceuticals as a financial controller.
IDT fell 0.4 cents or 4.3 percent to nine cents.

TISSUE REPAIR

Tissue Repair says the Automic Group's Dr Michael Austin has replaced Alistair McKeough as company secretary, effective immediately.
Tissue Repair said Dr Austin had more than five years' experience as a company secretary and that the appointment followed the resignation of Alistair McKeough.
According to his Linkedin page, Dr Austin held a Bachelor of Arts, Bachelor of Law and a Doctor of Philosophy from Macquarie University in Sydney.