Biotech Daily

Monday November 7, 2022

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: ANTISENSE UP 22%; PATRYS DOWN 5%**

*** TELIX: 'PHASE III TLX250-CDX KIDNEY IMAGING SUCCESS'**

*** POLYNOVO INDIA LAUNCH**

*** ARTRYA: BSI BACKS SALIX FOR UK APPROVAL**

*** CRONOS: ASX NO LONGER REQUIRES QUARTERLY REPORTS**

*** EUROPE TO GRANT AROVELLA CAR-INKT PLATFORM PATENT**

*** IDT WITHDRAWS 'VIRTUAL MEETINGS' AGM VOTE**

*** RESPIRI ENROLS 1st PATIENTS FOR WHEEZO REMOTE MONITORING**

*** PYC: VP-001 'NO ADVERSE EFFECTS' IN RABBITS, PRIMATES**

*** CANN GROUP, GSK OTC MARIJUANA CAPSULES DEAL**

*** AMPLIA APPOINTS FOUNDER DR CHRIS BURNS M-D, ON $350k PA**

MARKET REPORT

The Australian stock market was up 0.6 percent on Monday November 7, with the ASX200 up 41.2 points to 6,933.7 points. Thirteen of the Biotech Daily Top 40 stocks were up, 18 fell, six traded unchanged and three were untraded.

Antisense was the best on no news, up 1.8 cents or 21.95 percent to 10 cents, with 2.4 million shares traded. Impedimed improved 10.5 percent; Emvision climbed 9.15 percent; Paradigm was up 5.8 percent; Avita and Proteomics rose more than two percent; Amplia, Clinuvel, Cochlear, Cynata, Immutep and Orthocell were up one percent or more; with CSL, Medical Developments and Telix up by less than one percent.

Patrys led the falls, down 0.1 cents or 5.3 percent to 1.8 cents, with 2.5 million shares traded. Kazia, Resonance, Starpharma and Universal Biosensors fell four percent or more; Mesoblast, Micro-X, Next Science, Prescient, Resmed and Volpara were down more than three percent; Genetic Signatures, Imugene and Opthea shed more than two percent; Atomo was down 1.75 percent; with Nanosonics, Neuren, Polynovo and Pro Medicus down by less than one percent.

TELIX PHARMACEUTICALS

Telix says its 300-patient, phase III trial of TLX250-CDx for imaging clear-cell renal cancer met its primary endpoints, with 86 percent sensitivity and 87 percent specificity.

Telix said the trial met its “key secondary endpoint” of commensurate sensitivity and specificity of detecting clear-cell renal cancer in tumors of less than four centimetres in diameter “currently a significant clinical challenge”.

The company said that TLX250-CDx had the “potential to become a new clinical standard in the diagnosis of [clear-cell renal cancer] and deliver an unmet medical need for a non-invasive diagnostic tool [for this disease]”.

In July, Telix said it had dosed the final patient in the 300-patient, ‘Zircon’, confirmatory, prospective, multi-centre phase III study to examine the diagnostic, surveillance and staging ability of TLX250-CDx, imaging clear-cell renal cancer with positron emission tomography (PET) (BD: Jul 11, 2022).

Today, the company said the study met its primary endpoint of 84 percent or more sensitivity and specificity.

Telix said that TLX250-CDx “considerably exceeds confirmatory trial sensitivity and specificity success target of 70 percent”.

The company said that it had agreed with the US Food and Drug Administration that a sensitivity and specificity threshold of 70 percent would be the confirmatory trial objective, and that was the study goal.

A Telix spokesperson told Biotech Daily that the current method of diagnosis was a biopsy or a nephrectomy, that is, a resection of the kidney.

The company said that of the 300 patients dosed with TLX250-CDx, 284 patients were evaluable.

Telix said that each patient received a single dose of TLX250-CDx and a histological tumor sample from surgical resection was used as the truth comparator.

The company said that the trial showed the ability of TLX250-CDx “to reliably detect the clear cell phenotype and provide a non-invasive method of diagnosing the presence and spread of [clear-cell renal cancer]”.

Telix said the results meant that “for the first time, urologists and urologic oncologists may have a non-invasive way to determine if small renal masses are the clear cell phenotype, the most aggressive and common form of renal malignancy”.

The company said TLX250-CDx had breakthrough designation from the US Food and Drug Administration and it intended to file a biologics licence application with the FDA and other regulatory agencies for regulatory approval as a positron emission tomography/computed tomography (PET/CT) imaging agent for use in the characterization of indeterminate renal masses previously identified on CT or [magnetic resonance imaging] as clear-cell renal cancer or non-[clear-cell renal cancer].

Telix chief medical officer Dr Colin Hayward said “the excellent sensitivity and specificity” validated that the carbonic anhydrase IX (CAIX) target could as ground-breaking in clear-cell renal cancer as prostate-specific membrane antigen (PSMA)-PET imaging had been for prostate cancer.

“It could optimize surgical intervention, particularly in the incidence of very small renal masses,” Dr Hayward said. “These results provide confidence that TLX250-CDx is an important tool not only for initial diagnosis but potentially also for active surveillance and disease staging.”

Last year, Telix said the Australian Therapeutic Goods Administration had approved Illucix or 68-gallium PSMA-11 for prostate cancer imaging, followed by the US FDA and Health Canada (BD: Nov 2, 2021; Jan 16, Oct 14, 2022).

Telix was up five cents or 0.7 percent to $6.96 with two million shares traded.

POLYNOVO

Polynovo says it will launch its India operations at the Association of Plastic Surgeons of India annual conference on November 9, 2022.

Polynovo said that India was “considered among the top burns, trauma and diabetes capitals in the world” but that more than “90 percent of advanced dermal substitutes market is restricted to the US and Western Europe”.

Polynovo chief executive officer Swami Raote said the company had appointed an India-based managing-director and a chief medical officer.

Mr Raote said the company was are working with the Biomedical Advanced Research and Development Authority (BARDA) and the US Food and Drug Administration “to explore possibilities of using India to accelerate enrolment in our pivotal trials”.

Polynovo fell one cent or 0.5 percent to $2.03 with 1.3 million shares traded.

ARTRYA

Artrya says the British Standards Institute has recommended Conformity Assessed certification of the Salix coronary anatomy system for sale in the UK.

Last month, Artrya said that its European notified body, the British Standards Institute, had recommended Conformité Européenne (CE) mark for the Salix coronary anatomy system for coronary plaque identification.

Last year, the company said that Salix used artificial intelligence to automate the analysis and diagnosis of cardiac computed tomography (CT) scans, to help clinicians identify and manage patients at risk of a cardiac arrest, with a single CT scan able to detect and assesses the presence of vulnerable plaque in a patient’s arteries in about 15 minutes (BD: Oct 19, 2021).

Today, Artrya said the British Standards Institute said that Salix software “met or exceeded all regulatory requirements” for UK Conformity Assessed (UKCA) class two certification.

Artrya managing-director John Barrington said the approval was a “landmark moment”.

Mr Barrington said the company’s business activities in the UK were advanced and it was “well positioned to take advantage of the regulatory approval in this significant market”.

“This is Artrya’s biggest market opportunity to date and we aim to take full advantage of it,’’ Mr Barrington said

Artrya fell two cents or three percent to 64 cents.

CRONOS AUSTRALIA

Cronos says the ASX has enabled it to no longer file quarterly reports.

Cronos said that it had positive cash flows from operations for the previous four quarters, had cash equivalents of $19.49 million at September 30, 2022 and had a “history of sustained profitable trading and generation of increasing positive net cash flows from operations”.

The company said that, as a result, the ASX confirmed that it would be relieved of its quarterly reporting obligations.

Cronos chief executive officer Rodney Cocks said that “in yet another first for the Australian medicinal cannabis industry, Cronos Australia is proud to be the first company in the sector to be relieved of its obligations to file further quarterly reports”.

“The decision of [the] ASX is based on the positive net operating cash flows that the company has worked so hard to achieve,” Mr Cocks said.

Cronos was up half a cent or 0.6 percent to 86.5 cents.

AROVELLA

Arovella says the European Patent Office intends to grant a patent for its chimeric antigen receptor invariant natural killer T-cell (Car-INKT) platform for cancer treatment.
Arovella said that when granted, the patent, titled 'Transduction and expansion of cells', would protect its intellectual property until February 28, 2039.
Arovella was unchanged at 2.6 cents with 3.8 million shares traded.

IDT AUSTRALIA

IDT says it has withdrawn the annual general meeting resolution amending its constitution to allow it to hold "fully virtual general meetings".
IDT said that it had "become aware of reservations expressed about the use of fully virtual meetings by listed companies, and given the other proposed amendments are not considered to be material, the company has withdrawn the resolution".
IDT was unchanged at 10 cents.

RESPIRI

Respiri says it has enrolled the first patients in its remote patient monitoring study of its Wheezo asthma monitor, but did not disclose the total number of patients for the trial.
Respiri said the start of the study was not financially material but "marks a key milestone in the execution of the [company's] US business strategy".
Biotech Daily attempted to contact the company to clarify the study details but did not receive a response by the time of publication.
The company said that current procedural terminology (CPT) reimbursement codes for Wheezo remote patient monitoring would be processed and reimbursed by the US Centres of Medicare and Medicaid Services and other insurers within 45 days making Wheezo first "the first by an Australian [medical technology] company to be used for monetary reimbursement".
Respiri managing-director Marjan Mikel said "the enrolment of our first patients into the Wheezo [remote patient monitoring] program is significant as it confirms physicians acceptance of our technology and program as an important component of managing patients with asthma whilst ensuing reimbursement claims in the next month or so further validate our business strategy and model".
"We are now well into the US commercialization phase and expect to scale these programs and launch many more with other US-based healthcare organizations over the coming quarters, again supporting our chosen US business pathway," Mr Mikel said.
Respiri was up 0.6 cents or 16.2 percent to 4.3 cents.

PYC THERAPEUTICS

PYC says its single-dose VP-001 toxicology studies in rabbits and non-human primates was safe and well-tolerated with no adverse effects.
PYC said it combined two complementary platform technologies, RNA drug design capability and a proprietary drug delivery technology, to create an RNA therapeutic.
The company said it would file an investigational new drug application to the US Food and Drug Administration for VP-001 for the treatment of retinitis pigmentosa type 11 by January 2023 and progress into first in human studies by April 2023.
PYC was up 0.2 cents or 2.9 percent to 7.2 cents.

CANN GROUP

Cann Group says it has an agreement with Glaxosmithkline for the commercialization of its over-the-counter Satipharm marijuana cannabidiol (CBD) capsules.

In April, Cann Group said Glaxosmithkline Consumer Healthcare Australia, trading as Haleon, would pay GBP100,000 ($A173,000) to evaluate distribution and marketing of its Satipharm cannabidiol capsules and would have 60 days' exclusivity from the delivery of its final phase III Satipharm trial report, expected by early 2023, to evaluate the commercial potential of the low-dose product (BD: Apr 6, 2022).

Today, the company said it had signed a non-binding term sheet for the agreement, granting exclusive rights to Haleon, but did not disclose the commercial terms.

Cann Group fell half a cent or 2.1 percent to 23.5 cents.

AMPLIA THERAPEUTICS

Amplia says it has appointed founder Dr Christopher Burns as its managing-director, starting on $350,000 a year, effective from December 5, 2022.

Amplia said Dr Burns had more than 30 years of experience in drug discovery and development, and had been a chief executive officer for "a number of public and private biotechnology companies"

The company told Biotech Daily that Dr Burns was previously Cytopia's research director and worked with the Walter and Eliza Hall Institute initially as a laboratory head and later as a business development officer, and had been an executive with Occurx, Certa Therapeutics and Mycrx.

Amplia said that Dr Burns was an inventor on 15 patents and two drugs in clinical trials.

The company said that Dr Burns held a Bachelor of Science and a Doctor of Philosophy from the University of Melbourne.

Amplia said Dr Burns would be paid a base remuneration of $350,000 a year, with the potential for 25 percent of his base salary as short-term incentives, contingent on productivity goals and long-term incentives at the discretion of the board.

Amplia was up 0.1 cents or one percent to 10 cents.