Biotech Daily

Wednesday July 3, 2024

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: CYNATA UP 7%; DIMERIX DOWN 10.5%**

*** PETER MACCALLUM: 'CRISPR FOR CANCER'**

*** AMPLIA ENROLS PHASE IIa NARMAFOTINIB PANCREATIC CANCER TRIAL**

*** INHALERX SETS MARIJUANA IRX-211 PHASE II CANCER PAIN DOSE**

*** ISLAND $75k TO BIOCRYST FOR ANTI-VIRAL GALIDESIVIR OPTION**

*** IMMURON FILES $22.5m US SEC F-3 'AT-THE-MARKET' FORM**

*** TELIX TO RELEASE 5.4m VOLUNTARY ESCROW SHARES**

*** CEASING SUBSTANTIALS FOLLOW TELIX US IPO WITHDRAWAL**

*** EBOS TAKES 9.8% OF MEDADVISOR**

*** ALLAN GRAY REDUCES TO 7.9% OF STARPHARMA**

*** TREASURE CENTURY HOLDS 13% OF CAMBIUM**

*** APEX METRO HOLDS 9% OF CAMBIUM**

*** NEUREN LOSES 22-YEAR DIRECTOR DR TREVOR SCOTT**

MARKET REPORT

The Australian stock market was up 0.28 percent on Wednesday July 3, 2024, with the ASX200 up 21.7 points to 7,739.9 points. Sixteen of the Biotech Daily Top 40 stocks were up, 17 were down, six traded unchanged and one was untraded.

Cynata was the best, up two cents or 7.4 percent to 29 cents, with 56,558 shares traded. Paradigm and Percheron improved five percent or more; Amplia climbed 4.9 percent; Actinogen, Clarity, Medical Developments, Mesoblast and Universal Biosensors were up more than three percent; 4D Medical, CSL, Micro-X, Prescient, Resonance and Starpharma were up one percent or more; with Polynovo, Pro Medicus and Resmed up by less than one percent.

Dimerix led the falls, down 5.5 cents or 10.5 percent to 47 cents, with 9.5 million shares traded. Syntara lost 8.3 percent; Curvebeam was down 7.5 percent; Genetic Signatures fell 5.3 percent; Alcidion, Cyclopharm, Emvision, Next Science and Proteomics shed two percent or more; Immutep, Medadvisor, Neuren, Opthea and Orthocell were down one percent or more; with Avita, Clinuvel, Cochlear and Telix down by less than one percent.

PETER MACCALLUM CANCER CENTRE

The Peter MacCallum Cancer Centre says it is using Crispr technology to develop “rapid personalized cancer treatments by ‘cutting out’ disease-causing RNA”.

A media release from Melbourne’s Peter MacCallum Cancer Centre said that it had shown how the genome editing technology - clustered regularly interspaced short palindromic repeats (Crispr) - could “be adapted to target and destroy other disease-causing genes, including cancer-genes”.

The Centre said the study used the Cas9 protein found in Crispr technologies, which “cut” disease-causing sections of DNA but had been limited in its use in medicine because it could mistakenly cut healthy DNA.

The Peter MacCallum Centre said that its researchers had used the Cas13b Crispr protein to overcome the limitations of Cas9 and found the Cas13b protein could cut RNA with “high precision without harming DNA”.

The Centre said the study used a method called “single-base tiled screening and computer analysis to figure out how to make Cas13b more effective in cutting a target RNA in lab-grown human cells”.

The Peter MacCallum Centre said that by including further design parameters the researchers “upgraded Cas13b design to eliminate any RNA, including cancer RNA”.

The Centre said its research team had been re-engineering Cas13b tools for more than five years and had “initially engineered a version of Cas13b to silence the Covid-19 virus just after the beginning of the pandemic”.

The Centre said the research was conducted with the University of Melbourne and Sydney’s Children's Cancer Institute with the study, titled ‘Single-base tiled screen unveils design principles of PspCas13b for potent and off-target-free RNA silencing’, available at: https://go.nature.com/4ct9f4Q.

Peter MacCallum researcher and study lead Dr Mohamed Fareh said the “technology lays the foundation for bespoke treatments tailored to each patient”.

“DNA is the blueprint for every cell in the body, but RNA acts as a messenger, carrying information from DNA to produce proteins essential for healthy cells, cancer cells, or pathogenic viruses,” Dr Fareh said. “Cancer is often driven by abnormal RNA and targeting these ‘harmful RNAs' is akin to cutting off the cancer's supply chain”.

AMPLIA THERAPEUTICS

Amplia says it has enrolled all 26 patients in the first stage of its up-to 50-patient, two-stage, phase IIa trial of narmafotinib with chemotherapy for pancreatic cancer.

Earlier this year, Amplia said it dosed the first of up-to 50 patients in the trial of narmafotinib, formerly AMP945, for pancreatic cancer (BD: Jan 21, 2024).

Today, the company said enrolling the first stage of the trial, at six sites in Australia and five sites in South Korea, allowed it to conduct an interim analysis of the efficacy of narmafotinib with gemcitabine chemotherapy; with an efficacy assessment showing six or more partial or complete responses out of the 26 patients would “be sufficient to continue the trial” and it would then enrol an additional 24 patients.

Amplia managing-director Dr Chris Burns said the recruitment of the first stage of the trial was “an important milestone for the company”.

“With 26 patients enrolled, and based on experience to date, we believe that the outcome from the interim analysis will be reported around [October 2024]”, Dr Burns said. “Imaging data for the first patients from this cohort is now being collated and efficacy signals to date mirror the positive data previously reported from the phase Ib stage of the trial.”

Amplia was up 0.3 cents or 4.9 percent to 6.4 cents with 1.15 million shares traded.

INHALERX (FORMERLY LIFESPOT HEALTH)

Inhalerx says its 24-volunteer, phase I trial of its IRX-211 marijuana for cancer pain shows it is “well-tolerated” and has found an optimal dose for a phase II efficacy trial.

Last year, Inhalerx said it completed dosing its up-to-32 participant, phase I trial of IRX-211 evaluating safety, tolerability and pharmaco-kinetics, with a clinical study report expected by May 2024 (BD: Dec 4, 2023).

Today, the company said the results of the phase I study were “highly encouraging, indicated that IRX-211 is well-tolerated at all tested doses … [and] no dose-limiting toxicities were observed, and the pharmaco-kinetic profile supports progression to the next phase of clinical development”.

Inhalerx said it would proceed with the phase II trial to assess further efficacy and safety of its Dronabinol, or synthetic tetra-hydro-cannabinol (THC) marijuana, in a larger patient population.

Inhalerx chief executive officer Darryl Davies said completing the phase I study and the positive safety and tolerability data were “important milestones for Inhalerx”.

“We are excited to advance IRX-211 to phase II, bringing us one step closer to addressing breakthrough cancer pain with the goal of improving patient outcomes,” Mr Davies said.

Inhalerx was untraded at 2.5 cents.

ISLAND PHARMACEUTICALS

Island says it will pay Durham, North Carolina’s Biocryst Pharmaceuticals $US50,000 ($A74,900) for the option to acquire its galidesivir anti-viral molecule.

Island said Biocryst had a molecule that exhibited “anti-viral activity against several different viruses including Ebola, Zika and Marburg, for which there are no currently approved therapies”.

The company said it had the option to purchase galidesivir within 12 months, and that it would use the period to “perform additional due diligence and consult with advisors on the optimal clinical and regulatory strategies”.

Island said upon the exercise of its option to purchase the asset it would pay Biocryst $US500,000 to acquire the rights, title and interest in the program.

The company said it would pay a further $US500,000 on completing a phase II clinical trial with the drug and $US1 million if approved for a new drug application in the US, or equivalent, or $US1.5 million if no phase II trial was required.

Island said it would pay Biocryst royalties of five-to-10 percent of net sales and 25 percent of the proceeds from the sale of any priority review voucher awarded due to US Food and Drug Administration approval of galidesivir.

The company said it had not executed a definitive option agreement and neither party was bound until the option agreement was executed, expected by October 2024.

Island managing-director Dr David Foster said the identification of galidesivir followed “more than three years of research from Island into a variety of molecules as part of our pipeline diversification strategy”.

“In a follow-on asset to ISLA-101, we were looking for something that already had safety data,” Dr Foster said.

“We were also seeking a small molecule which had anti-viral activity and was eligible for a priority review voucher,” Dr Foster said.

“It needed to fit in with our interest in supporting national and military preparedness, with potential to attract non-dilutive funding in support of clinical studies,” Dr Foster said.

“We feel that galidesivir ticks each of these boxes,” Dr Foster said.

Island fell half a cent or 6.5 percent to 7.2 cents.

IMMURON

Immuron says it has filed a US Securities and Exchange Commission F-3 form, allowing it to offer up-to $US15 million ($A22.5 million) over three years.
In 2019, Immuron said it had lodged a Form F-3 with the US SEC to allow it to raise up-to $US100 million until April 2022 (BD: Apr 2, 2019).
Today, the company said the replacement F-3 form superseded its previous form and allowed it to maintain its “flexibility with direct access to US capital markets”.
Immuron said it had an at-the-market facility with New York’s HC Wainwright & Co to provide it with access to about $US2 million in funding.
The company said it would “control major aspects of the placement process, having sole discretion as to whether it uses the [at-the-market facility], the number of American depository shares issued, as well as the minimum issue price”.
Immuron was unchanged at 8.2 cents.

TELIX PHARMACEUTICALS

Telix says it will release 5,436,966 shares from three-month voluntary escrow on July 10, 2024 as part of its acquisition of ARTMS Inc.
Earlier this year, Telix said it had completed its up-to $US82.0 million ($A126.1 million) acquisition of the Vancouver, British Columbia-based radio-isotope production company ARTMS Inc (BD: Apr 11, 2024).
According to its most recent filing, following the release of the shares from voluntary escrow Telix will have 334,251,398 shares available for trading.
Telix fell three cents or 0.2 percent to $18.32 with 767,358 shares traded.

TELIX PHARMACEUTICALS

A group of companies have ceased their substantial shareholdings in Telix after the withdrawal of its US initial public offer.
Earlier this year, Morgan Stanley, Jeffries, First Sentier, Truist Securities and William Blair said they became substantial in Telix with up-to 55,952,009 shares, or up-to 16.75 percent (BD: May 22, 2024).
Today, in six separate substantial shareholder notices, the companies said they ceased their holdings in Telix “as a result of termination of the lock-up agreements in relation to Telix’s public offering in the US of American depository shares”.
Last month, Telix said it had withdrawn its proposed $350 million US initial public offer to list on the Nasdaq (BD: Jun 14, 2024).

MEDADVISOR

The Melbourne-based EBOS Group says it has become a substantial shareholder in Medadvisor with 53,986,463 shares, or 9.81 percent.
EBOS said that on July 3, 2024 it bought 27,527,196 shares for $13,763,598, or 50 cents a share.
The company said that it initially acquired a 14.1 percent interest in Medadvisor in October 2017, which had been diluted and “regards its shareholding in Medadvisor as an investment and does not intend to make a change of control proposal in respect of Medadvisor”.
Medadvisor fell half a cent or one percent to 48 cents with 29.0 million shares traded.

STARPHARMA HOLDINGS

Allan Gray Australia Pty Ltd says it has reduced its substantial shareholding in Starpharma from 38,239,700 shares (9.28%) to 32,599,963 shares (7.91%).
The Sydney-based Allan Gray said that between June 22 and June 28, 2024 it sold 5,639,737 shares for $508,544, or an average of 9.0 cents a share.
Starpharma was up 0.1 cents or 1.1 percent to 9.4 cents.

CAMBIUM BIO (FORMERLY REGENEUS)

Treasure Century Group Ltd says it became substantial in Cambium with 99,900,109 shares, or 16.3 percent, and was diluted in a capital raise to 13.04 percent.
The Eden Island, Seychelles-based Treasure Century Group said that it acquired the 99,900,109 shares on April 5, 2024 for no consideration through the “acquisition of interest by swap the Cambium’s shares”.
Earlier this year, the then Regeneus said it had raised $3.48 million in a placement at 0.6 cents a share, to fund non-clinical studies of Elate Ocular and prepare for phase III trials as well as general working capital purposes (BD: Apr 5, 2024).
Cambium was untraded at 0.4 cents.

CAMBIUM BIO (FORMERLY REGENEUS)

Apex Metro Investments Ltd says it became substantial in Cambium with 69,157,904 shares (11.28%), and was diluted in a capital raise to 9.03 percent (see above).
The Apia, Samoa-based Apex Metro Investments said it acquired the 69,157,904 shares on April 5, 2024 for no consideration through the “acquisition of interest by swap the Cambium’s shares”.

NEUREN PHARMACEUTICALS

In an Appendix 3Z final director’s interest notice, Dr Trevor Scott said he had ceased to be a director of Neuren on June 30, 2024.
In the company’s annual general meeting address on May 28, 2024, Neuren chair Patrick Davies said Dr Scott had intended to “retire as a director of Neuren at the end of June 2024 after a period of some 22 years”.
Mr Davies said Dr Scott had “made an immeasurable impact, especially during the most challenging times on Neuren’s journey”.
“It has been a delight to work with Trevor and I wish him every possible happiness as he enjoys his well-earned free time post-June 30, and thank him for his extraordinary contribution,” Mr Davies said.
Neuren fell 20 cents or one percent to $19.90 with 369,529 shares traded.