Biotech Daily

Thursday May 3, 2018

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: STARPHARMA UP 12%; CYNATA DOWN 6.5%**

*** IMMUTEP CEO MARC VOIGT: 'MULTIPLE TRIALS, MULTIPLE MILESTONES'**

*** STARPHARMA, MUNDIPHARMA UP-TO-$12m VIVAGEL BV DEAL**

*** ANTISENSE $4.5m RIGHTS OFFER COMPLETES $5m RAISE**

*** CE MARK FOR MEDIBIO CARDIAC MENTAL ILLNESS DIAGNOSTIC**

*** G MEDICAL, ZINGMOBILE $4m PRIZMA SMARTPHONE CASE ASIA DEAL**

*** CANN TELLS ASX: 'AURORA TALKS CONFIDENTIAL UNTIL THEY WEREN'T'**

*** G MEDICAL AGM: 28% OPPOSE DR BRENDAN DE KAUWE ELECTION**

*** ASX LIFTS ESENSE COMPULSORY SUSPENSION**

MARKET REPORT

The Australian stock market was up 0.8 percent on Thursday May 3, 2018 with the ASX200 up 48.1 points to 6,098.3 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 13 fell, 12 traded unchanged and one was untraded. All three Big Caps were up.

Starpharma was the best, up 14 cents or 11.8 percent to $1.325 with 1.6 million shares traded.

Universal Biosensors climbed 10 percent; Ellex was up 8.6 percent; Immutep and Reva improved more than four percent; LBT and Orthocell were up three percent or more; Clinuvel, Medical Developments, Prana and Telix rose more than two percent; Cochlear, ITL and Opthea were up one percent or more; with CSL, Impedimed and Resmed up by less than one percent.

Cynata led the falls, down eight cents or 6.5 percent to $1.15 with 691,321 shares traded.

Optiscan lost 5.4 percent; Airxpanders and Osprey were down more than three percent; Benitec and Factor Therapeutics shed more than two percent; Avita, Bionomics, Genetic Signatures and Mesoblast were down one percent or more; with Neuren, Polynovo and Sirtex down by less than one percent.

IMMUTEP

Immutep chief executive officer Marc Voigt says the company has four drugs in trials ranging from pre-clinical to phase IIb with the potential for multi-million-dollar milestone payments.

In Melbourne for a series of investor meetings, Mr Voigt detailed the company's trial program and said that the company's compounds were currently in trials with Glaxosmithkline and Novartis, and a new combination trial was planned to begin in November with Merck Inc providing pembrolizumab, marketed as Keytruda, for the study.

Mr Voigt said told Biotech Daily that the trials were progressing well and positive results would result in "multi-million-dollar" milestone payments.

Mr Voigt said that the company was conducting its own 24-patient, phase I, two active immune-therapeutics in melanoma (Tacti-mel) trial of lead compound IMP321 with pembrolizumab for melanoma.

He said the Tacti-mel trial comprised an 18-patient dose escalation phase and a six-patient extension looking for the sub-optimal responders to be treated with the combination therapy.

Mr Voigt said that results were expected this month but "the interim results were good enough for Merck to supply Keytruda for the Tacti-002 trial".

Mr Voigt said the up-to-120-patient, open-label phase II, Tacti-002 combination trial of IMP321 with pembrolizumab would be in lung cancer and head and neck cancer at sites in the European Union, the US and Australia and begin recruiting in November 2018.

He said that the trial would look for pre-defined responses in the first 60 patients before progressing to further patients.

Mr Voigt said that Glaxosmithkline was paying for the phase I trial of the cyto-toxic T-cell depleting antibody IMP731, for organ transplant rejection and auto-immune disease, which began in 2015 before the then Prima acquired Immutep, and was completed in March 2018 with results later this year (BD Dec 17, 2014).

"We are optimistic about the potential future of that product and if successful it will lead to a phase II trial with GSK paying all the costs and very significant multi-million-dollar milestones," Mr Voigt said.

Mr Voigt said that IMP701 was an immune checkpoint inhibitor in three separate phase II trials with Novartis enrolling a total of about 1,000 patients.

"We do not have data from these trials but the number of trials and milestone payments is encouraging," Mr Voigt said.

"With these two partners [Glaxosmithkline and Novartis] we really are running well," Mr Voigt said.

Mr Voigt said that IMP321, also known as eftilagimod alpha, was currently in an up-to 226-patient, phase IIb trial in seven European Union countries for HER2-negative, hormone receptor-positive metastatic breast cancer.

He said that the active immunotherapy paclitaxel (Aipac) trial was in combination with paclitaxel, marketed by Bristol-Myers Squibb as Taxol, with progression-free survival results expected in mid-2019.

Mr Voigt said that the open-label, phase I, investigator-initiated 'Insight' trial of IMP321 would enrol 18 patients with solid tumors to investigate intra-tumoral and intra-peritoneal injections of the compound in a single centre in Frankfurt, Germany, to determine the recommended dose for each administration route for an intended phase II clinical trial.

Mr Voigt said that IMP761 was in pre-clinical studies in cynomolgus monkeys and was intended to switch-off T-cells for auto-immune diseases including multiple sclerosis, lupus and colitis.

Immutep was up 0.1 cents or 4.2 percent to 2.5 cents with 8.1 million shares traded.

STARPHARMA

Starpharma says it will receive a $1.3 million up-front payment in an up to $12.2 million 15-year licence with Mundipharma to market and sell Vivagel BV for bacterial vaginosis.
Starpharma said that the Singapore-based Mundipharma would market, sell and be "responsible for regulatory activities" for its Vivagel BV in China, Japan, Korea, the Middle East, Africa and "the majority of Latin America".
The company said it was eligible to receive signing, regulatory and commercial milestones of up to $12.2 million and that the agreement included minimum annual purchases.
Starpharma said Vivagel BV would be registered and launched by Mundipharma as part of the Betadine range.
Starpharma chief executive officer Dr Jackie Fairley said the licence was "a financially attractive deal for Starpharma".
"Over the coming months, we'll be working closely with Mundipharma to secure market access for Vivagel BV as quickly as possible throughout their territory," Dr Fairley said.
Starpharma it was in "advanced commercial negotiations for marketing rights to Vivagel BV in the rest of world, including North America and Europe".
Starpharma climbed 14 cents or 11.8 percent to $1.325 with 1.6 million shares traded.

ANTISENSE THERAPEUTICS

Antisense says it has raised $5 million through its placement to Australian Ethical Investment and a one-for-one non-renounceable entitlement offer (BD: Apr 3, 2018).
Antisense said that it received acceptances for 81,089,870 shares, raising $1.95 million and resulting in a shortfall of 104,703,449 shares or $2.5 million.
The company said that the lead manager for the placement and the entitlement offer XEC Partners had binding priority commitments of $3.5 million from new investors and existing shareholders, including Australian Ethical Investment, Platinum Asset Management, CVC, Leon Serry and clients of XEC Partners and sufficient to cover the shortfall.
Antisense said the funds would be used to complete the phase II ATL1102 Duchenne muscular dystrophy trial and begin the ATL1103 acromegaly early access program.
Antisense fell 0.1 cents or 3.85 percent to 2.5 cents.

MEDIBIO

Medibio says it has Conformité Européene (CE) mark approval for its Logic mental illness diagnostic platform and is applying for approval in other jurisdictions.
Medibio chief executive officer Jack Cosentino told Biotech Daily the CE mark approval was for the company's Logic platform and algorithms to aid in the diagnosis of depression.
Mr Cosentino said the product addressed the "Medibio Mental Index product for monitoring and management of mental illness, including depression".
In a media release to the ASX, the company said the Logic platform allowed physicians and individuals "to evaluate stress-level phenotypes, combined with dimensional circadian heart-sleep biometrics and physiological biometrics".
Medibio said its software application and web-based mental health diagnostic platforms allowed "non-invasive, comprehensive evaluation and monitoring of mental health".
Mr Cosentino said that CE mark approval was "the successful completion of a lengthy and thorough evaluation process and marks an important threshold for the company".
"Alongside the recent announcement of our corporate mental health product, this accomplishment provides further validation of the product … and technology," he said.
Medibio was up three cents or 17.65 percent to 20 cents with 2.1 million shares traded.

G MEDICAL INNOVATIONS

G Medical says it has received a $US3 million ($A4 million) conditional purchase order from Singapore-based Zingmobile for its Prizma Medical smartphone case.

G Medical said that under the purchase order Zingmobile would distribute the Prizma smartphone cases with vital signs sensors and become the G Medical distributor for Singapore and 10 other markets in South East Asia, including The Philippines, Malaysia, Thailand and Indonesia.

The company said that the purchase order was conditional on the regulatory certifications clearance and local carrier approval for each individual country and translating and localizing the user interface of Prizma Medical smartphone cases.

G Medical was unchanged at 29.5 cents.

CANN GROUP

Cann has told an ASX aware query that discussions with Aurora Cannabis were not reported to the ASX as they were preliminary and held on a confidential basis.

The ASX noted Cann's announcement regarding media speculation of the rumoured takeover and asked whether the information in the announcement would be "information that a reasonable person would expect to have a material effect on the price or value of its securities" and when it first became aware of the information.

Cann said that it became aware of its discussions with Aurora on April 21, 2018 but said that it did not make an announcement to the ASX as "the preliminary discussions between the company and Aurora Cannabis Inc were held on a confidential basis".

The company said the information "concerned an incomplete proposal or negotiation and was insufficiently definite to warrant disclosure".

Cann said that on the morning of April 30, 2018 it became aware of an article in the Australian Financial Review and "formed the view that the information ceased to be confidential" and "promptly and without delay, prepared and released its announcement to the market on the same morning prior to any trading of the company's shares on ASX" and said there was "no certainty that any formal offer or transaction will eventuate" (BD: Apr 30, 2018).

According to its most recent substantial shareholder notice, the $C4.3 billion ($A4.4 billion) Toronto Stock Exchange-listed and Vancouver, British Columbia-based Aurora owned 22.9 percent of Cann Group.

Cann fell 42 cents or 10.9 percent to $3.43 with 1.1 million shares traded.

G (GEVA) MEDICAL INNOVATIONS

G Medical's annual general meeting passed all resolutions but with 15,112,309 votes (27.8%) opposed to the election of director Dr Brendan De Kauwe.

G Medical said director Ashley Krongold's election was withdrawn prior to the meeting. Mr Krongold was appointed a director in September 2017 and resigned in April, without citing a reason (BD: Sep 19, 2017; Apr 24, 2018).

Today, G Medical said that all other resolutions were passed easily with up to four million votes against the approval of a 10 percent placement facility and 108,292 votes against the election of director Sam Skantos, with more than 53.6 million votes in favor.

According to the most recent G Medical Appendix 3B new issue announcement the company had 339,668,619 shares on issue, meaning the vote against the election of Dr De Kauwe amounted to 4.45 percent of the company, insufficient to requisition extraordinary general meetings.

ESENSE-LAB

The ASX says the suspension of Esense has been lifted 2018, “following release of the company’s quarterly reports and receipt of satisfactory responses to ASX queries”

Esense recently emerged from a board spill extraordinary general meeting in which it alleged that it had been unable to access its funds (BD: Feb 21, Mar 23, 29, Apr 3, 2018).

Esense fell two cents or 12.1 percent to 14.5 cents.