# Biotech Daily

Thursday May 23, 2019

*Daily news on ASX-listed biotechnology companies*

*** ASX DOWN, BIOTECH UP: LBT UP 14%; OPTISCAN DOWN 9%**

*** STARPHARMA: 'BACTERIAL VAGINOSIS TRIAL POSSIBLE, FDA TALKS'**

*** ADALTA RAISES $5m, RIGHTS OFFER FOR $2m MORE**

*** GENETIC TECHNOLOGIES ADSs RAISE $1.75m**

*** IMAGION TOXICOLOGY STUDY: 'MAGSENSE SAFE FOR BREAST CANCER'**

*** IMMUTEP IMP321, CHEMOTHERAPY PATENT FOR EUROPE**

*** NOXOPHARM EXPANDS NOX66 PROSTATE CANCER TRIAL**

*** FMR TAKES 5% OF SOMNOMED**

*** G MEDICAL 2m DIRECTOR SHARES, 14.5m CEO LOAN SHARES AGM**

*** MICRO-X 'LATE CLEANSING NOTICE' TRADING HALT**

*** CRESO HARVESTS FIRST CANADIAN MARIJUANA CROP**

## MARKET REPORT

The Australian stock market fell 0.29 percent on Thursday May 23, 2019, with the ASX200 down 18.9 points to 6,491.8 points. Seventeen of the Biotech Daily Top 40 stocks were up, 15 fell, six traded unchanged and two were untraded.

LBT was the best, up two cents or 14.3 percent to 16 cents, with 9.0 million shares traded. Medical Developments and Orthocell climbed more than seven percent; Imugene was up 5.9 percent; Osprey improved 4.35 percent; Opthea and Pharmaxis were up more than three percent; Clinuvel, Kazia, Polynovo and Pro Medicus rose more than two percent; Avita, Cochlear, Dimerix and Proteomics were up more than one percent; with Genetic Signatures, Paradigm, Resmed and Volpara up by less than one percent.

Optiscan led the falls, down 0.4 cents or 9.1 percent to four cents, with 217,945 shares traded. Actinogen lost 7.1 percent; Antisense and Uscom fell more than five percent; Immutep was down 3.45 percent; Alterity, Oncosil and Universal Biosensors shed more than two percent; Cyclopharm, Mesoblast, Starpharma and Telix were down more than one percent; with Compumedics, CSL, Nanosonics and Neuren down by less than one percent.

## STARPHARMA HOLDINGS

Starpharma says it is prepared for a new clinical trial of Vivagel BV for bacterial vaginosis should the US Food and Drug Administration require one.

Starpharma said it had been in talks with the FDA regarding its application for Vivagel BV for treatment of bacterial vaginosis and prevention of recurrence of bacterial vaginosis and already had fast track status and qualified infectious disease product (QIDP) status for both indications.

The company said that should a new trial be required, it "would be in a position to commence a [bacterial vaginosis] treatment trial quickly" following a previous US trial that was completed in less than four months and cost less than $US4 million ($A5.8 million).

Starpharma said it was working through various options to recognise the positive impact of approval for one indication on the other and its focus would be "to pursue the most expeditious and efficient path to approval".

Late last year, the company said the FDA had requested "confirmatory clinical data" to approve Vivagel in the US (BD: Jan 20, 2019).

In shareholder updates, Starpharma said it wasn't sure if the request was for a further trial and a meeting would "allow the company to clarify what clinical data will be required and whether this will be through the generation of new confirmatory clinical data, or whether the requirement can be satisfied by additional analyses of existing clinical data".

Today, Starpharma chief executive officer Dr Jackie Fairley said the company was "pleased that the FDA interactions continue to be constructive and focused on the path to approval".

"The FDA's feedback also clearly highlights the recognition of the significant unmet medical need that could be fulfilled by Vivagel BV," Dr Fairley said.

"Having received formal feedback, we are now thoroughly investigating the possible options with a view to pursuing the optimal approval strategy to secure access to the US market as soon as possible," Dr Fairley said.

"We continue to believe in the strength of the extensive data package for Vivagel BV which has supported multiple approvals around the world, including Europe and Australia, and we look forward to the upcoming European launch of the product," Dr Fairley said.

Starpharma fell 1.5 cents or 1.15 percent to $1.285 with 834,254 shares traded.

## ADALTA

Adalta says it has raised $5 million in an "oversubscribed" placement at 15 cents a share and hopes to raise up to $2 million in a one-for-8.8 rights issue at the same price.

Adalta said that investors would receive one option for every two new shares acquired, exercisable at 25 cents a share by June 30, 2021.

The company said the placement to sophisticated and professional investors would be in two tranches with the second tranche, subject to shareholder approval.

Adalta said the 15 cents offer was an 18.9 percent discount to the closing price on May 21, 2019 and a 16.9 percent discount to the 15-day volume-weighted average price.

The company said funds would be used "to progress AD-214 to a major value inflection point", for a phase I study to show the compound's safety, to provide materials for clinical studies and to expand its pipeline, general working capital and corporate costs.

Adalta said the record date for the rights issue would be May 28, with the offer opening on May 31 and closing on June 12, 2019.

The company said Aurenda Partners and Bell Potter Securities were joint lead managers and Bell Potter was the bookrunner for the placement.

Adalta climbed five cents or 27.0 percent to 23.5 cents.

## GENETIC TECHNOLOGIES

Genetic Technologies says it has raised $US1.2 million ($A1,745,064) through the sale of 1,476,143 American depositary shares (ADSs) at 80 US cents ($A1.163).
Genetic Technologies said that each ADS was equivalent to 150 Australian shares, implying the capital raise was equivalent to 0.775 cents a share.
The company said it would issue warrants (options) over 1,107,107 ADSs, exercisable at 80 US cents a share within five years of issue.
Genetic Technologies said proceeds would be used for general product and research and development, for expansion in the People's Republic of China and to fund the development of polygenic risk tests with the Phoenix, Arizona-based Translational Genomics Research Institute (TGen)
The company said Aegis Capital Corp was the exclusive placement agent for the raise.
Genetic Technologies fell 0.1 cents or 11.1 percent to 0.8 cents with 13.0 million shares traded.

## IMAGION BIOSYSTEMS

Imagion says a toxicology study of the Magsense nanoparticle formulation for breast cancer shows the compound is safe, with no adverse effects.
Imagion said its Magsense device used iron oxide magnetic nanoparticles to detect human epidermal growth factor receptor 2 (HER2) metastatic breast cancer.
The company it would use its safety findings to file applications to regulatory and clinical authorities for first-in-human testing.
Imagion was up 0.3 cents or 12.5 percent to 2.7 cents with 3.2 million shares traded.

## IMMUTEP

Immutep says it has a European patent for combined therapeutic preparations of eftilagimod alpha, or IMP321, and a chemotherapy agent.
Immutep said the patent, titled 'Combined Preparations for the Treatment of Cancer' would protect its intellectual property until December 19, 2034.
The company said the patent covered either a platinum-based anti-neoplastic chemotherapy agent or a topoisomerase I inhibitor chemotherapy agent, such as topotecan.
Immutep fell 0.1 cents or 3.45 percent to 2.8 cents with 1.2 million shares traded.

## NOXOPHARM

Noxopharm says it will recruit a further 24 patients to be treated with 1,200mg of NOX66 and 177Lu-PSMA-617 for prostate cancer.
Last year, Noxopharm said it was approved to increase the number of patients in its phase I NOX66 trial for late-stage prostate cancer to 32 patients (BD: Sep 5, 2018).
On Monday, the company said five of eight 400mg dose patients and six of eight 800mg dose prostate cancer patients had prostate specific antigen (PSA) responses when treated with NOX66 and 177-Lu-PSMA-617 (BD: May 20, 2019).
Today, Noxopharm said the 24 patients would receive 1,200mg of NOX66 with 177-Lu-PSMA-617 for 10 days.
The company said this would "lay the foundations for a pivotal phase II/III registration trial".
Noxopharm was up one cent or 1.7 percent to 60 cents.

## SOMNOMED

FMR says it has become a substantial shareholder in Somnomed with 3,290,467 shares or 5.24 percent.
The Boston, Massachusetts-based FMR said it bought 1,319,547 shares between March 8 and May 20, 2019 at prices ranging from $1.65 to $1.87 a share.
Somnomed fell four cents or 2.2 percent to $1.76.

## G (GEVA) MEDICAL INNOVATIONS

G Medical says it proposes to re-elect directors and issue shares, options and performance rights in its annual general meeting.
G Medical said it would vote to issue 500,000 shares each to Dr Kenneth Melani, Dr Shuki Gleitman, Dr Brendan de Kauwe and Urs Wettstein “as part of the consideration for services provided since admission of the company to the official list on the ASX, including unpaid director fees”.
The company said it would vote to issue 100,000 options to Sam Skontos exercisable at 20 cents each within two years of issue, 250,000 shares to Grange Consulting Group “in lieu of corporate secretarial fees” and 500,000 performance rights to director Prof Zeev Rotstein.
G Medical said it would vote to ratify the issue of 3,325,000 shares to Acuity Capital Investment Management and to issue 14,532,771 loan shares to founder and chief executive officer Dr Yacov Geva.
The company said it would vote to approve the election of Prof Rotstein as a director and to re-elect directors Mr Wettstein and Dr Gleitman.
G Medical said it would vote on a special resolution for the 10 percent placement facility.
The meeting will be held at SMC Conference and Function Centre, 66 Goulburn Street, Sydney, on June 24, 2019 at 10am (AEST).
G Medical was up 1.5 cents or 7.9 percent to 20.5 cents.

## MICRO-X

Micro-X has requested a trading halt pending an announcement in relation to its late cleansing notice.
Yesterday, Micro-X told the ASX that it was late in filing its cleansing notice due to an administrative oversight.
Trading will resume on May 27, 2019 or on an earlier announcement.
Micro-X fell half a cent or 1.7 percent to 28.5 cents.

## CRESO PHARMA

Creso says its subsidiary Mernova Medical has harvested its first Canadian marijuana crop at its Nova Scotia facility.
Creso said its facility was running at full capacity, was ahead of schedule and was moving towards revenue.
The company said it was progressing its European certification process for companies in Germany, Italy, Spain and Switzerland.
Creso fell one cent or 2.2 percent to 45 cents.