

Biotech Daily

Wednesday September 27, 2017

Daily news on ASX-listed biotechnology companies

* ASX DOWN, BIOTECH FLAT: STARPHARMA UP 4%, LBT DOWN 8%

- * CNBP COMPUTER-ASSISTED CYSTOSCOPY FOR BLADDER CANCER
- * AUS BIO SINGLE DROP DRUG PREVENTS INFLUENZA IN MICE, FERRETS
- * PSIVIDA \$1.2m DEAL FOR GLAUCOMA DRUGS
- * OPTISCAN PLAN RAISES \$1.2m, \$2.3m TO GO
- * RECCE SHARE PLAN FOR UP TO \$1m
- * LBT AUTOMATED PLATE ASSESSMENT SYSTEM TRIAL BEGINS
- * NEUROTECH: MENTE AUTISM 'INCREDIBLE PRELIMINARY RESULTS'
- * NOXOPHARM TO BEGIN PHASE Ib NOX66 PROSTATE CANCER TRIAL
- * US PATENT FOR CYNATA STEM CELL SCALABILITY
- * MEMPHASYS SETTLES \$4.5m PRIME, PULAU MANUKAN DISPUTE

MARKET REPORT

The Australian stock market fell 0.12 percent on Wednesday September 27, 2017 with the ASX200 down 6.7 points to 5,664.3 points. Fourteen of the Biotech Daily Top 40 stocks were up, 13 fell, eight traded unchanged and five were untraded.

Starpharma was the best, up five cents or 4.2 percent to \$1.24 with 1.2 million shares traded. Avita, ITL, Orthocell and Viralytics climbed more than three percent; Living Cell and Psivida rose more than two percent; Ellex, Impedimed, Mesoblast, Neuren and Pro Medicus were up more than one percent; with Cochlear, Nanosonics, Resmed and Sirtex up by less than one percent.

LBT led the falls, down 2.5 cents or 7.7 percent to 30 cents with 804,803 shares traded. Actinogen, Opthea and Pharmaxis lost more than five percent; Cellmid fell four percent; Benitec was down 3.85 percent; Factor Therapeutics, Osprey and Uscom shed more than two percent; Airxpanders, Bionomics, Clinuvel and Polynovo were down more than one percent; with CSL down 0.08 percent.

THE CENTRE FOR NANOSCALE BIO-PHOTONICS

The Centre For Nanoscale Bio-Photonics (CNBP) says it has developed a computerized imaging and analysis of lesions to aid the diagnosis of bladder cancer.

The Centre said that technique allowed suspect lesion images to be quickly and effectively analyzed and classified for cancer risk.

The CNBP said a research article on the system, entitled 'Computer-assisted cystoscopy diagnosis of bladder cancer' was published in the Elsevier Science Direct journal Urologic Oncology: Seminars and Original Investigations' and was available at:

http://www.sciencedirect.com/science/article/pii/S107814391730460X.

The paper concluded that "based on criteria used for assessment of cystoscopy images by medical specialists and features that human visual system is less sensitive to, we developed a computer program that carries out automated analysis of cystoscopy images".

"Our program could be used as a triage to identify patients who do not require referral or further testing," the paper concluded.

Lead author and CNBP researcher Dr Martin Gosnell said that cystoscopy was "one of the most reliable methods for diagnosing bladder cancer".

"Images are taken of the bladder and its insides for suspicious lesions during a routine clinical patient evaluation," Dr Gosnell said. "Dependent on the findings, this initial scan can then be followed up by a referral to a more experienced urologist and a biopsy of the suspicious tissue can be undertaken."

Dr Gosnell said the clinician examining the images made a visual judgement on the next steps, such as the need to for a biopsy for subsequent pathological analysis.

"Potential errors and unnecessary further interventions may result from the subjective character of this initial visual assessment," Dr Gosnell said.

"What we've done is to create an automated image analysis technique which can identify tissue and lesions as either high-risk or minimal-risk ...[which] is beneficial on multiple levels," Dr Gosnell said.

"Following the analysis, high-risk diagnoses can be followed up more closely as a matter of urgent priority ... [and] minimal-risk lesions can be identified early in the diagnostic process, reducing the number of referrals or biopsies," Dr Gosnell said.

The CNBP's deputy director Prof Ewa Goldys said the lesion classification system was developed using a colour segmentation process.

"Images which were taken during routine clinical patient evaluations and supported by biopsy were interpreted by an expert clinician ... [and] classified as either healthy, veined tissue, inflammation or cancerous ... based on aspects such as colour, surface, shape and size of the lesion or tissue of interest."

Prof Goldys said the Centre devised a computerized method that mimicked the diagnoses and provided a clear-cut classification system: the presence or non-presence of specific characteristics in the image aligning with the healthy or cancerous nature of the tissue being examined.

"Using our innovative computer program, 100 percent of the cancerous images were detected and all benign lesions were also successfully identified," Prof Goldys said.

"This system would be particularly useful in supporting less experienced urologists and urology nurses, giving them an objective confirmation of their assessment ... [and] has the potential to reduce the number of patients being given erroneous assessments or unnecessary bladder biopsies."

The Centre said it was a \$40 million Australian Research Council Centre of Excellence with sites at the University of Adelaide, Macquarie University and the Royal Melbourne Institute of Technology.

AUS BIO LTD

The Melbourne-based Aus Bio says mice and ferrets studies show the effectiveness of its single dose anti-influenza drug compounds to prevent and treat infections.

Aus Bio said the University of Melbourne conducted the studies and the data was presented at the Global Network Virus Meeting at the Peter Doherty Institute, yesterday. The University of Melbourne department of microbiology and immunology's Prof Lorena Brown said the preclinical research was "very promising".

"Our results have indicated that these anti-influenza compounds are extremely potent and have long lasting effectiveness against a wide range of 'flu viruses including influenza A and B, and the subtype H3N2, the predominant circulating influenza A virus in Australia this year," Prof Brown said.

Aus Bio said that influenza vaccines were "the cornerstone of controlling influenza infections in the community, [but] antiviral treatments are also vital".

The company said that anti-virals complemented vaccination programs by treating influenza and helping to stop the spread of new strains that had changed since the vaccine was prepared.

Aus Bio said its anti-influenza drug compounds stopped influenza infections by disabling the virus before it entered the respiratory cell, with a single intranasal drop of five micrograms 12 days before infection completely preventing the disease in mice.

Aus Bio said that current antivirals needed to be given twice daily for several days starting within 48 hours of an influenza infection, but its drug candidates would treat infections when given once only, up to 72 hours after infection had occurred.

"As the influenza virus gets smarter and more resistant to our drugs, we need to get smarter with our research to tackle this public health challenge," Prof Brown said.

"These preclinical studies are a great example of the ingenuity of the Aus Bio scientists who have developed a novel way to control the infection," Prof Brown.

"I will be delighted to see this translate into better health outcomes for people, particularly the young and old who face the greatest risk of serious complications from influenza," Prof Brown said.

Aus Bio said that the pre-clinical results showed that the drug compounds were highly effective against the avian influenza viruses H5N1 and H7N9, both of which had pandemic potential.

Aus Bio is a public unlisted company.

<u>PSIVIDA</u>

Psivida says it has an up to \$1,205,306 agreement with an unnamed pharmaceutical company to use its sustained delivery technology for two glaucoma drugs.

The company said the agreement included an upfront payment of \$US750,000

(\$A951,580), with a further \$US200,000 (\$A253,726) if all subsequent development work was conducted .

Psivida chief executive officer Nancy Lurker said it was the second collaboration agreement in 2017.

"This agreement extends the strong working relationship between the two organizations," Ms Lurker said.

"Glaucoma is one of the major causes of blindness and many patients are not compliant with administering the commonly prescribed daily drops," Ms Lurker said.

Ms Lurker said Psivida's sustained release technology had the potential to provide new dosing options in combination with the two glaucoma drugs.

Psivida climbed 4.5 cents or three percent to \$1.56.

OPTISCAN IMAGING LIMITED

Optiscan says its underwritten share plan has raised \$1,188,000 from 166 applications for 14,850,000 shares at eight cents each.

Optiscan said that the share plan was underwritten by Paterson Securities to \$2,500,000 and brokers would place the shortfall of 16,400,000 shares to raise a further \$1,312,000. The company said it had commitments from professional and sophisticated investors for a \$1,000,000 placement at the same price.

In August, Optiscan said the funds would be used to meet orders from partner Carl Zeiss Meditech, meet the expected product demand for its Viewnvivo systems, fund sales and marketing costs as well as research and development activities and working capital. Optiscan was up 0.1 cents or 1.2 percent to 8.4 cents.

RECCE

Recce says it hopes to raise up to \$1,000,000 through a share plan at 17.5 cents a share. Recce said shareholders eligible at the record date of September 26, 2017 would be able to apply for parcels of shares up to \$15,000.

The company said the offer would open on October 3 and close on October 18, 2017. Recce said the funds would be used for its investigational new drug application to the US Food and Drug Administration for its Recce 327 antibiotic and for working capital. Recce fell 4.5 cents or 20 percent to 18 cents.

LBT INNOVATIONS

LBT says that Melbourne's St Vincent's Hospital has begun the first in-situ evaluation of its Automated Plate Assessment System (APAS).

LBT said the US Food and Drug Administration-approved APAS Independence instrument was being commercialized with Clever Culture Systems AG, a joint venture company between LBT and the Switzerland-based Hettich AG (BD: Oct 10, 2016).

The company said APAS was used for "automated imaging, image analysis, interpretation and reporting of growth on microbiology plates after incubation".

LBT said the APAS was the size of a large photocopier and improved "the clinical efficiency of microbiology laboratories and enables faster diagnosis and reporting of infectious diseases".

The company said that training of staff at St Vincent's Hospital began this week.

LBT said the trial at St Vincent's Hospital would "enable the evaluation of the instrument's performance and provide valuable feedback in a diagnostic pathology laboratory".

The company said that the current method required microbiologists and scientists to individually review agar plates, of which up to 95 percent returned negative results.

LBT said its APAS "rapidly and automatically reviews and sorts plates into neat stacks of positives, negatives and plates to be reviewed; at a rate of 200 plates per hour".

The company said it expected St Vincent's evaluation by the end of this year.

LBT said the APAS Independence would be evaluated at additional microbiology centres during the next 18 months.

The company said successful trials at the reference laboratories would be a precursor to a commercial roll-out of the APAS system.

LBT fell 2.5 cents or 7.7 percent to 30 cents.

NEUROTECH INTERNATIONAL

The Malta-based Neurotech says it has "incredible preliminary results" for its Mente Autism device with many children scoring "in a normal range after the treatment". The company said the study findings were presented by Bedfordshire Centre for Mental Health Research senior researcher Prof Frederick Carrick at the Cambridge International Conference on Mental Health, at Clare College, Cambridge, England, September 20 to 22, 2017, but did not provide specific data from the trial.

Neurotech said the Mente Autism head band measured a child's brain waves and changed sound to match the needs of the child, with treatment given for 40 minutes each morning of the 12-week trial.

Bedfordshire senior researcher Dr Ahmed Ankir said "we are thrilled to review these incredible preliminary findings and are looking forward to the publication of the final study". Neurotech said children with autism spectrum syndrome were divided into two groups, with one receiving Mente Autism and the other receiving a placebo.

Prof Carrick said the effect of the Mente Autism device had "statistical significance". "The study is ongoing but half of the children in our study have completed it and we have observed major positive changes in the children in the active arm of the study and no statistical changes in the control group of children that did not receive the active treatment," Prof Carrick said.

Prof Carrick said he expected the study to be finalised by the end of the year. Neurotech jumped 18.5 cents or 112.1 percent to 35 cents with 13.8 million shares traded.

NOXOPHARM

Noxopharm says it hopes to start its 24-patient phase lb trial of NOX66 for metastatic castrate-resistant advanced prostate cancer by the end of October 2017.

Noxopharm said the trial, at five centres in Queensland and New South Wales was being overseen by the Trans-Tasman Radiation Oncology Group Cancer Research Australia. The company said NOX66, or idronoxil, would be used in combination with radiotherapy and some tumors would be left un-irradiated "to determine their response to treatment". Noxopharm said that NOX66 was being used as a radio-sensitizer with the objective of sensitizing cancer cells to radiation so that a low dose would lead to better tumor responses and increased patient survival.

The company said that 12 patients would be treated prior to a safety review.

Noxopharm said patients would have radiotherapy for seven days and then receive NOX66 daily for the following two weeks in cohort doses of 400mg, 800mg and 1200mg. The company said patients would be scanned at three and six months "to determine the extent of any response in both irradiated and non-irradiated tumors, and the durability of any response" with all 24 patients expected to be enrolled by April 2018.

Noxopharm chief executive officer Dr Graham Kelly said the study would investigate "whether NOX66 can make those tumors exposed to radiotherapy go from a typical partial response of short-term shrinkage, to a more significant response involving longer-term complete remission ... [and] "whether NOX66 can go beyond that direct radio-sensitizing effect to an indirect radio-sensitizing effect where all those other cancers in parts of the body not exposed to radiotherapy, also respond".

Noxopharm said that trials of NOX66 were underway for late-stage prostate cancer in combination with radiotherapy and 177-lutetium-prostate specific membrane antigen (Lupsma), and with carboplatin in patients with late-stage breast, lung, ovary, prostate, head and neck cancer (BD: May 29, Jun 5, 2017).

Noxopharm was up one cent or 3.2 percent to 32.5 cents.

CYNATA THERAPEUTICS

Cynata says the US Patent and Trademark Office has granted a patent covering scalability of its Cymerus mesenchymal stem cell technology.

Cynata said that the patent, entitled 'A method of making primate cells expressing apelin receptor that have mesangioblast potential' covered certain methods relating to the platform's ability to efficiently manufacture mesenchymal stem cells at scale.

The company said that the patent was owned by the University of Wisconsin–Madison's Wisconsin Alumni Research Foundation and was part of the intellectual property licenced exclusively to Cynata.

Cynata said that the inventors named on the patent were Dr Maxim Vodyanyk and Prof Igor Slukvin, who were founders, advisors and shareholders of Cynata.

The company said the patent provided protection until February 1, 2028.

Cynata chief executive officer Dr Ross Macdonald said the company was "delighted that the USPTO has granted this patent, building further strength in Cynata's comprehensive patent portfolio".

"Our proprietary Cymerus stem cell manufacturing technology enables the scalable manufacture of consistent, high-quality mesenchymal stem cell therapeutic products targeting a range of devastating diseases worldwide," Dr Macdonald said. Cynata was up 2.5 cents or 3.8 percent to 68 cents.

MEMPHASYS

Memphasys says it has settled all of its disputes Prime Biologics Pte Ltd and Pulau Manukan Ventures Labuan.

Memphasys said that Manukan had full rights and ownership over the preference B shares in Prime formerly owned by Memphasys and Memphasys was clear of the \$\$4,821,623 (\$A4,520,500) debt, with the \$250,000 debt plus interest fully repaid to Crescendas Projects Pte Ltd.

In July Memphasys said it had reached a settlement on all disputes following mediation with Pulau Manukan Ventures Labuan and Prime Biologics (BD: Jul 27, 2017).

The company said in July that it had consented to Manukan's full rights and ownership over the preference B Shares in Prime which were subject of a call option deed and Prime and Manukan would no longer pursue any claim against Memphasys in relation to the \$S4.8 million debt associated with equipment at the Prime facility in Singapore, believed to be the GF100 blood separator (BD: Feb 17, 2017).

Memphasys was up 0.1 cents or 33.3 percent to 0.4 cents with one million shares traded.