



Biotech Daily

Monday June 19, 2017

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: DIMERIX UP 14%, PSIVIDA DOWN 5%**
- * **MEDLAB READY FOR 2 MEDICAL MARIJUANA TRIALS**
- * **REVA COMPLETES \$45m RAISING**
- * **US PATENT FOR CYNATA STEM CELLS**
- * **RESAPP: 'SMARTCOUGH-C TRIAL RECRUITED, RESULTS IN JULY'**
- * **MGC: MIKRO+POLO FOR SLOVENIA, CROATIA, BOSNIA CANNABIS SALES**
- * **PRESCIENT PTX-100 TARGETS NEW CANCER PATHWAY IN MICE**
- * **NEUROTECH SIGNS ATTIEH FOR SAUDI ARABIA MENTE AUTISM SALES**
- * **ESENSE SIGNS BEYOND BRANDS FOR TERPENE MARKETING, SALES**
- * **RON SHAMGAR, THE BOAT FUND BELOW 5% OF ITL**
- * **NOXOPHARM NOX66 '1,000 X MORE EFFECTIVE' FOR BRAIN CANCER**

MARKET REPORT

The Australian stock market was up 0.54 percent on Monday June 19, 2017 with the ASX200 up 31.2 points to 5,805.2 points. Thirteen of the Biotech Daily Top 40 stocks were up, 15 fell, nine traded unchanged and three were untraded.

Dimerix was the best, up 0.1 cents or 14.3 percent to 0.8 cents with 10.2 million shares traded. Opthea climbed 9.3 percent; Neuren improved 5.45 percent; both Osprey and Universal Biosensors were up four percent; Bionomics was up 3.8 percent; Atcor, Compumedics, Ellex, Polynovo and Pro Medicus rose more than two percent; Medical Developments was up 1.1 percent; with CSL, Resmed and Sirtex up by less than one percent.

Psivida led the falls, down 13 cents or 5.1 percent to \$2.43 with 2,865 shares traded. Avita and Pharmaxis lost more than three percent; Acrux, Airxpanders, LBT, Nanosonics, Prana, Starpharma, Uscom and Viralytics shed more than two percent; Clinuvel, Factor Therapeutics and Oncosil were down more than one percent; with Cochlear and Mesoblast down less than one percent.

MEDLAB CLINICAL

Medlab says it has ethics approvals for trials of two different cannabis-based drugs Nanabis and Nanabidial with different applications to be studied at different locations. Medlab said that Nanabis would be trialled in advanced stage cancer patients with intractable pain at the Sydney-based Royal North Shore Hospital's Cancer Centre, supervised by Prof Stephen Clarke.

The company said that Nanabis would be administered by its Nanocelle nano-particle spray to the inside of the cheek to assess safety, efficacy and tolerability.

Medlab said that Nanabis was a proposed schedule 8 drug and combined cannabidiol and tetrahydrocannabinol and the study would form the basis for an Australian Therapeutic Goods Administration special access scheme application.

The company said that Nanabidial contained cannabidiol and the trial would be a safety trial in healthy individuals with completion expected within six months.

Medlab said that it proposed that Nanabidial be indicated for chemotherapy-induced nausea and vomiting, with a secondary endpoint in patients suffering seizures and would be administered by the Nanocelle delivery platform.

The company said that the study would form the basis for a TGA special access scheme to enable prescription by general practitioners.

Medlab chief executive officer Sean Hall said that the start of the clinical trials was "a significant breakthrough for Australian medicine".

"Nanabidial is intended to be made available to [general practitioners] so it would give many Australians access to a drug which governments around the country have been keen to see introduced," Mr Hall said.

"While time lines can't be predicted with accuracy, it is possible Medlab may have these medicines on the market later in 2018 should [special access scheme] applications be successful," Mr Hall said.

"Our research with cannabis also indicates potential for other related conditions, creating a distinctive positioning for the research from a medical and market perspective," Mr Hall said.

Medlab said that Nanabidial was developed with Nanabis and together they would "provide a significant increase in market potential by ultimately allowing a prescriptive, therapeutic agent".

The company said the trials were expected to begin "shortly".

Medlab was up 2.5 cents or 3.1 percent to 82 cents.

REVA MEDICAL

Reva says it has completed the \$US13.3 million (\$A17.5 million) second tranche of its capital raising taking the total to \$US34.6 million (\$45.4 million).

Reva said it issued a total of \$US47.1 million in convertible notes and options and repurchased \$US12.5 million of its common stock from one of the participating investors. Reva chief executive officer Dr Reggie Groves stated said the funds provided the capital "for our near and longer-term operating plans".

"The timing of the funding coincides with our commercial launch of Fantom, which is the most advanced bio-resorbable scaffold available to treat patients suffering from coronary artery disease and our initiation of the expanded clinical trials of Fantom," Dr Groves said. Reva was untraded at 86 cents.

CYNATA THERAPEUTICS

Cynata says the US Patent and Trademark Office has allowed a patent relating to its Cymerus mesenchymal stem cell technology.

Cynata said that the patent application, entitled 'A method of making primate cells expressing apelin receptor that have mesangioblast potential' was owned by the University of Wisconsin–Madison's Wisconsin Alumni Research Foundation and was part of the intellectual property licenced by Cynata and, if granted, the patent would be granted by October 2017, with an expiration date of February 1, 2028.

Cynata chief executive officer Dr Ross Macdonald said the patent application covered "an important element of our proprietary Cymerus stem cell manufacturing technology".

"This patent and others we have filed continue to strengthen our comprehensive patent portfolio relating to the scalable manufacture of consistent, high-quality mesenchymal stem cell therapeutic products targeting a range of devastating diseases worldwide." Dr Macdonald said.

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

Cynata was up two cents or 3.3 percent to 63 cents.

RESAPP HEALTH

Resapp says it has completed enrolment of the 1,245 patients in the Smartcough-C trial of its respiratory diagnostic.

In May, Resapp said that with 1,157 patients enrolled in its Smartcough-C trial the initial phase of the trial was "nearing completion" with top-line results, expected in July (BD: May 30, 2017).

Today, the company said it had "exceeded its target recruitment numbers for all study endpoints including those for pneumonia, upper respiratory tract infection, lower respiratory tract involvement, croup, asthma [and] reactive airways disease and bronchiolitis".

Resapp was up half a cent or 1.6 percent to 31.5 cents.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says Mikro + Polo DOO will be the exclusive distributor of its cannabis active pharmaceutical ingredients for government tenders in Slovenia, Croatia and Bosnia. MGC said that the Maribor, Solvenia-based Mikro + Polo was "the largest Slovenian supplier of laboratory accessories, equipment, chemicals and diagnostics" providing more than 500,000 products to research institutions, academies and laboratories, including government customers such as the University of Ljubljana and the Institute of Public Health Maribor.

The company said that cannabis ingredients would be supplied to Mikro + Polo at an agreed price based on the underlying market price of EUR60 (\$A88.20) per gram.

MGC said the raw materials would be sourced from its growing facilities in the Czech Republic Europe and processed into active pharmaceutical ingredient in its extraction facility in Slovenia (BD: Apr 28, Jun 15, 2016; Apr 10, 2017).

The company said that its laboratory, clean room and extraction facility was in the formal good manufacturing practice certification process in the Republic of Slovenia.

MGC fell 0.1 cents or 2.1 percent to 4.7 cents with 18.9 million shares traded.

[PRESCIENT THERAPEUTICS](#)

Prescient says that a pre-clinical study of its geranylgeranyl transferase inhibitor GGTI-2418, now known as PTX-100, plays a key role in mitigating a new cancer pathway. Prescient said that the pathway was discovered by New York University's Langone Medical Center's Prof Michele Pagano in collaboration with the company's chief scientific officer Prof Said Sebti.

The company said that the research demonstrated new details about the tumor suppressor gene PTEN which was defective in 30 to 60 percent of certain breast, brain and uterine cancers.

"When defective, PTEN cannot control a protein known as FBXL2, which is thought to be responsible for cancer growth in many patients," Prof Pagano said.

Prescient said that the study showed that when administered with PTX-100 with photodynamic therapy FBXL2 was switched-off in mice, allowing abnormal cells to self-destruct.

The company said that patients whose tumors had defective PTEN might also be more likely to respond to a combination of PTEN and photodynamic therapy.

"These findings have important translational implications for Prescient as patients whose tumors harbor defective PTEN may be more likely to respond to a combination of PTX-100 and photodynamic therapy," Prof Sebti said.

"Furthermore, given that PTEN is known to also suppress the Akt tumor survival pathway, patients with PTEN defective tumors could respond to a combination of PTX-100 and an Akt inhibitor like PTX-200," Prof Sebti said.

Prescient chief executive officer Steven Yatomi-Clarke said the discovery of "a new cancer-causing pathway targeted by PTX-100 is an exciting development for Prescient". "This discovery opens up a new frontier of clinical possibilities for PTX-100," Mr Yatomi-Clarke said.

Last month, Prescient said it paused recruitment to trials of PTX-200 following the death of the last of 29 patients in its phase Ib breast cancer trial (BD: May 29, 2017).

Prescient was up 0.4 cents or 7.7 percent to 5.6 cents.

[NEUROTECH INTERNATIONAL](#)

Neurotech says it has signed Attieh Medico as its exclusive marketing and distribution partner for its Mente Autism diagnostic and training system in Saudi Arabia.

Neurotech said that Attieh Medico was based in Jeddah, with branches in Riyadh and other regions of Saudi Arabia.

The company said it would provide in-depth training to Attieh Medico personnel, with several marketing initiatives planned in the coming months.

Neurotech fell one cent or 3.85 percent to 25 cents.

[ESENSE-LAB](#)

Esense says it has a memorandum of understanding with product development and marketing firm Beyond Brands for its terpenes plant extract-based products.

Esense said that the New York-based Beyond Brands would undertake "a multi-faceted approach for branding, marketing, product development, securing contract manufacturing with other US facilities for other delivery formats, such as beverages, as well as distribution channels and partners".

Esense was up 1.5 cents or 6.4 percent to 25 cents.

ITL

Ron Shamgar and The Boat Fund Investment Management say the sale of 161,500 ITL shares has reduced them below the five percent substantial shareholding level.

In February, the Sydney-based The Boat Fund Investment Management said it became substantial in ITL with 4,850,000 shares or 5.06 percent, buying shares at prices ranging from 37.5 cents to 50 cents a share. (BD: Feb 20, 2017)

Today, Mr Shamgar said the Fund sold the shares on-market at prices between 55 and 57 cents.

Biotech Daily calculates that Mr Shamgar and the Boat Fund retain 4,688,500 shares or 4.9 percent of ITL.

ITL was unchanged at 53 cents.

NOXOPHARM

Noxopharm claims an in-vitro study shows that the idronoxil makes temozolomide one thousand times more effective against secondary brain cancer.

Noxopharm did not provide any data from, or details of, the laboratory studies but said that idronoxil was the active component of its NOX66 and that temozolomide was used as a chemotherapy agent against breast cancer and melanoma.

The company said that secondary brain cancer was a prominent cause of death of cancer patients, with the incidence three-times greater than primary brain cancer.

Noxopharm said it was working with universities and research institutions in Australia and Hong Kong to bring NOX66 into the clinic in 2018 for aggressive brain cancer.

Noxopharm chief executive officer Dr Graham Kelly said the blood-brain barrier was “a key hurdle in delivering more effective treatments for patients with cancers involving the brain”.

“We know that [temozolomide] crosses that barrier as does idronoxil, at least in animals when delivered in the form of NOX66,” Dr Kelly said.

“So here we have two drugs capable of reaching cancerous lesions within the brain and which we now know act in a highly synergistic way,” Dr Kelly said.

“I need to stress that this is in-vitro data, so it needs to be seen in that context, but it is the critical first step that we needed to verify and for that reason should not be underestimated,” Dr Kelly said.

“To the best of my knowledge, this is the first time that anyone has reported being able to turn the fairly modest anti-cancer action of [temozolomide] into a potent cancer-killing effect,” Dr Kelly said.

Noxopharm was up one cent or 2.6 percent to 40 cents.