



Biotech Daily

Thursday June 20, 2019

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH EVEN: COMPUMEDICS UP 10%; ORTHOCELL DOWN 5%**
- * **PHARMAXIS: 'FDA WANTS SMALL CLINICIAN BRONCHITOL STUDY'**
- * **NUHEARA IQBUDS BOOST ON NHS SCOTLAND HEARABLES CONTRACT**
- * **ASHLAND \$3.6m AVECHO (PHOSPHAGENICS) VITAL ET, TPM LICENCE**
- * **MEDIBIO: 'HEART ALGORITHM 80% ACCURATE FOR DEPRESSION'**
- * **TGA REGISTERS OVENTUS EXVENT FOR SLEEP APNOEA**
- * **BOTANIX: 'BTX1801 KILLS SUPER BUGS IN-VITRO, IN MICE'**
- * **JEFFREY EMMANUEL TAKES 8.5% OF BARD1**
- * **MERCHANT FUNDS TAKES 7.7% OF BARD1**
- * **DAVID WILLIAMS, MOGGS CREEK, TAKE 5.5% OF BARD1**
- * **KINETIC TAKES 5.6% OF OSPREY**
- * **KINETIC TAKES 5.6% OF IMPEDIMED**
- * **IMMURON VICE-CHAIRMAN PETER ANASTASIOU TAKES 11%**
- * **MACH7 DAVID CHAMBERS, DAMIEN LIM SWAP CHAIRS, MIKE LAMPRON M-D**

MARKET REPORT

The Australian stock market was up 0.59 percent on Thursday June 20, 2019, with the ASX200 up 39.3 points to 6,687.4 points. Fourteen of the Biotech Daily Top 40 stocks were up, 13 fell, nine traded unchanged and four were untraded. All three Big Caps rose.

Compumedics was the best, up six cents or 10 percent to 66 cents, with 124,411 shares traded. Telix climbed 9.1 percent; Antisense, Medical Developments and Pro Medicus improved more than four percent; Nanosonics and Pharmaxis rose more than two percent; Avita, Benitec, Dimerix, Oncosil, Polynovo and Starpharma were up more than one percent; with Cochlear, CSL, Opthea and Resmed up by less than one percent.

Orthocell led the falls, down 2.5 cents or 5.1 percent to 46.5 cents, with 6.6 million shares traded. Osprey fell 4.65 percent; Kazia and LBT were down more than three percent; Ellex, Neuren and Universal Biosensors shed more than two percent; with Clinuvel, Cynata, Genetic Signatures, Mesoblast, Proteomics and Volpara down by less than one percent.

PHARMAXIS

Pharmaxis says the US Food and Drug Administration requires a small clinician study to approve Bronchitol for adult cystic fibrosis patients, expected by the end of 2019.

Pharmaxis said its US licensee, the Parma, Italy-based Chiesi Group received a complete response letter from the FDA detailing the remaining matters to be addressed before Bronchitol could be approved in the US.

The company said that the main requirement was that Chiesi revise the product packaging and user instructions and conduct "a human factor study" showing that the revised user components enabled healthcare professionals to properly administer the mannitol tolerance test.

Pharmaxis chief financial officer David McGarvey told Biotech Daily that clinicians needed to ensure that patients did not have airways reactions to Bronchitol's active ingredient mannitol.

Mr McGarvey said that the study required that "a small number of clinicians need to demonstrate that the new instructions are simple and easy to follow".

In a media release, the company said that "based upon the clear and achievable path to approval communicated in the FDA complete response letter, Pharmaxis believes that the FDA review of the Bronchitol [new drug application] will be completed [by April] 2020.

Pharmaxis chief executive officer Gary Phillips said that the FDA changes to product packaging and user instructions and human factor study was "targeted for completion by the end of 2019".

"Based on our experience with healthcare professionals in other markets where our training and packaging has supported thousands of mannitol tolerance tests that have been conducted to ensure patients hypersensitive to mannitol are not prescribed Bronchitol, we are very confident the requested FDA changes can be efficiently implemented and will be effective in achieving the desired goal," Mr Phillips said.

"We have been sharing our experiences in other markets with Chiesi and continue to work collaboratively to prepare for a successful introduction to patients in US cystic fibrosis clinics," Mr Phillips said.

Pharmaxis said that Chiesi was responsible for the regulatory approval and commercialization of Bronchitol in the US.

The company said that if Bronchitol was approved by the FDA, it would receive a \$US10 million milestone payment on the commercial launch of Bronchitol in the US "and mid to high teen percentage royalties on ... net sales".

Pharmaxis said it would manufacture and be the exclusive supplier of Bronchitol for the US market.

The company said that Bronchitol was approved and marketed in Europe, Russia, Australia and several other countries.

Pharmaxis was up half a cent or 2.1 percent to 24.5 cents.

NUHEARA

Nuheara says its Iqbuds Boost is on the UK National Health Service Scotland hearing contract under the Hearables category for streaming and hearing enhancing devices. Nuheara said Iqbuds Boost would be available immediately through its contract with the UK-based distributor Puretone.

The company said the Scotland contract had 14 National Health Service health boards and covered Northern Ireland.

Nuheara was unchanged at 7.3 cents with 2.2 million shares traded.

[AVECHO BIOTECHNOLOGY \(FORMERLY PHOSPHAGENICS\)](#)

Avecho says Ashland Global will pay \$US2.5 million (\$A3.6 million) to manufacture its Vital ET and tocopheryl phosphate mixture vitamin E-based products.

Avecho said the Covington, Kentucky-based Ashland would develop, manufacture and sell its Vital ET and tocopheryl phosphate mixture (TPM) globally for the one-time payment, through subsidiary ISP Investments LLC.

The company said Ashland currently held global distribution rights for Vital ET and would acquire all interests to manufacture the products.

Avecho said Ashland would be granted a right of first refusal for its manufacturing patents, allowing it to submit a matching offer should Avecho receive an offer from a third party.

The company said it would retain intellectual property rights to manufacture TPM for human and animal health applications and to meet existing contracts.

Avecho executive chairman Dr Greg Collier said that the deal was a “positive outcome ... providing an injection of non-dilutive capital and strengthening our cash position”.

“This payment locks in and brings forward revenue that we may have expected to accrue over a four-plus year period,” Dr Collier said.

“Based on our current cash burn of approximately \$1.7 million per year, and the associated reduction in manufacturing costs, this is a meaningful extension to our cash runway,” Dr Collier said.

Avecho was unchanged at 0.3 cents with 3.9 million shares traded.

[MEDIBIO](#)

Medibio says its heart rate algorithm is 79.9 percent accurate for diagnosing depression and could be used as a physiological marker for depression.

Last year, Medibio said its cardiac rhythm diagnostic algorithm showed 70 percent sensitivity and 71 percent specificity in diagnosing a major depressive episode over four scans (BD: Sep 6, 2018).

Today, the company said the research, titled ‘Using heart rate profiles during sleep as a biomarker of depression’ was published in BMC Psychiatry and the article is at:

<https://bmcp psychiatry.biomedcentral.com/articles/10.1186/s12888-019-2152-1>.

Medibio said the University of Ottawa in Ontario study measured changes in heart rate across sleep-wake states to identify depression in sleep complainants.

The research study said the heart rate profiling algorithm used machine-learning on 1,203 poly-somnograms from 664 individuals with depression referred to sleep clinics and 529 healthy controls and found that the algorithm classified 79.9 percent of individuals accurately, detected 82.8 percent of depression cases (sensitivity) and ruled out 77.0 percent (specificity) of healthy controls.

Medibio said primary care practitioners had a detection rate of about 47 percent.

Medibio was unchanged at 0.8 cents with 1.9 million shares traded.

[OVENTUS MEDICAL](#)

Oventus says its Exvent valve accessory for O2Vent devices for obstructive sleep apnoea has been registered with the Australian Therapeutic Goods Administration.

Oventus said it would begin sales of the device in Australia and Canada in conjunction with a program to sleep groups and physicians.

The company said it expected to make Exvent available in the US in late 2019, subject to US Food and Drug Administration 510k approval.

Oventus was unchanged at 20.5 cents.

BOTANIX PHARMACEUTICALS

Botanix says its cannabidiol formulation BTX1801 kills super bugs without resistance in a proof-of-concept study in-vitro and in a mouse model of bacterial wound infection.

Botanix said that BTX1801 was delivered using its Permetrex delivery technology and killed a broad range of gram-positive human and animal bacteria.

The company said BTX1801 was used against 132 clinical isolates of staphylococcus aureus and methicillin-resistance staphylococcus aureus (MRSA).

Botanix said BTX1801 was effective in low concentrations, bacteria did not form resistance in repeat challenge tests and MRSA bacteria did not form resistance after 21 days of treatment.

The company said the cannabidiol killed bacteria in less than three hours and disrupted biofilms used by bacteria to protect themselves against antibiotics.

Yesterday, Botanix said its 15-patient, phase Ib, mechanism-of-action study of BTX1308 for psoriasis showed an anti-inflammatory response and immune cell modulating activity (BD: Jun 19, 2019).

The company said it found inflammatory disease pathways, including the p38 mitogen-activated protein (MAP) kinase pathway and interleukin-6 (IL-6) pathway, were downregulated in psoriatic skin treated with BTX1308.

Today, Botanix said BTX1801 showed broad anti-inflammatory properties through the same anti-inflammatory pathway for cannabidiol in skin disease.

The company said it would optimize its dosing strategy for BTX1801 and proceed with a clinical study in a target skin infection indication.

Botanix was up 6.5 cents or 46.4 percent to 20.5 cents with 75.8 million shares traded.

BARD1 LIFE SCIENCES

Jeffrey Emmanuel says he has become a substantial shareholder in Bard1 with 105,179,166 shares or 8.46 percent.

The Hong Kong-based Mr Emmanuel said that on June 18, 2019 he acquired 92,500,000 shares for \$1,850,000 or two cents a share, and at various dates, acquired 12,679,166 shares for \$316,979 or 2.5 cents a share.

On Tuesday, Bard1, in announcing its \$4.97 million placement at 2.0 cents a share, said Mr Emmanuel worked for the Hong Kong-based EFM Asset Management.

Bard 1 was up 0.1 cents or 4.55 percent to 2.3 cents with 11.8 million shares traded.

BARD1 LIFE SCIENCES

Merchant Funds Management says it has become a substantial shareholder in Bard1 with 95,440,211 shares or 7.68 percent.

The Perth, Western Australia-based Merchant Funds said that between December 19, 2018 and June 18, 2019, it bought 118,999,963 shares, with the single largest purchase 62,500,000 shares for \$1,250,000 or two cents a share on June 18, 2019.

On Tuesday, Bard1 said it raised \$4.97 million in a placement at 2.0 cents a share to investors including the Merchant Opportunities Fund (BD: Jun 18, 2019).

Today, Merchant said that between April 9 and May 15, 2019 it sold 23,909,752 shares for prices ranging from 1.9 cents a share to two cents a share.

[BARD1 LIFE SCIENCES](#)

Moggs Creek director David Williams says he has become a substantial shareholder in Bard1 with 68,500,000 shares or 5.51 percent.

The Melbourne-based Mr Williams said that on June 18, 2019 he acquired the 68,500,000 shares for \$1,370,000 or two cents a share.

On Tuesday, Bard1 said that Mr Williams was the principal of advisory firm Kidder Williams as well as the chairman of Medical Developments, Polynovo and RMA Global (BD: Jun 18, 2019).

[OSPREY MEDICAL](#)

Kinetic Investment Partners says it has become a substantial shareholder in Osprey with 23,764,199 shares of 5.60 percent.

The Melbourne-based Kinetic said that between June 12 and 18, 2019, it acquired 4,364,609 shares for \$401,544 or 9.2 cents a share.

Osprey fell 0.4 cents or 4.65 percent to 8.2 cents with 1.15 million shares traded.

[IMPEDIMED](#)

Kinetic Investment Partners says it has become a substantial shareholder in Impedimed with 21,107,504 shares or 5.56 percent.

The Melbourne-based Kinetic said that between June 12 and 18, 2019, it acquired 4,656,564 shares for \$618,879 or 13.2 cents a share.

Impedimed was unchanged at 11.5 cents with 3.1 million shares traded.

[IMMURON](#)

Immuron executive vice chairman Peter Anastasiou says he has increased his holding in the company from 17,336,144 shares (10.62%) to 17,836,144 shares (10.93%).

The Melbourne-based Mr Anastasiou said that on June 19, 2019, through his company Grandlodge Pty Ltd, he bought 500,000 shares on-market for \$57,500 or 11.5 cents a share.

Immuron was up half a cent or 4.8 percent to 11 cents.

[MACH7 TECHNOLOGIES](#)

Mach7 says from June 24, 2019 David Chambers will replace Damien Lim as chair with interim chief executive officer Mike Lampron appointed managing-director.

Mach7 said that Mr Lim would continue as a non-executive director.

The company said that the change of chairs was "the first step of a planned board renewal process" and it would conduct a search for a new director who has deep healthcare and information technology experience.

Mach7 was up seven cents or 16.7 percent to 49 cents.