



Biotech Daily

Wednesday June 6, 2018

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: ELLEX UP 7%; AIRXPANDERS DOWN 13%**
- * **AVITA RAISING \$16m FOR RECELL US LAUNCH**
- * **ORTHOCELL: POSITIVE INTERIM CELLGRO SHOULDER TRIAL RESULTS**
- * **ZELDA: 'MARIJUANA EXTRACTS REDUCE BRAIN CANCER IN-VITRO'**
- * **NANOSONICS: US ULTRASOUND DECONTAMINATION NON-COMPLIANCE**
- * **LBT REVIEW AXES WOUNDVUE FOR APAS FOCUS**
- * **ATOMO, OWEN MUMFORD PARTNER FOR RAPID HIV TESTS**
- * **BOTANIX: 'SYNTHETIC CANNABIDIOL BTX1204 FOR ECZEMA SAFE, EFFICACY'**
- * **CANN, LA TROBE UNI EXPAND MARIJUANA R&D**
- * **ESENSE MARIJUANA E-LIQUID FOR VAPORIZING**
- * **US ALLOWS RESAPP DIAGNOSTIC PATENT**
- * **ADMEDUS REQUESTS 'SUPPLY TERMINATION' TRADING HALT**
- * **NUHEARA REQUESTS CAPITAL RAISING TRADING HALT**
- * **FIL REDUCES TO 7% OF STARPHARMA**
- * **CLARITY APPOINTS MICHELLE PARKER FOR CLINICAL OPERATIONS**
- * **CAMERON PETRICEVIC REPLACES ALCHEMIA DIRECTOR DAVID LAMM**

MARKET REPORT

The Australian stock market was up 0.5 percent on Wednesday June 6, 2018 with the ASX200 up 30.2 points to 6025.1 points. Twelve of the Biotech Daily Top 40 stocks were up, 19 fell, four traded unchanged and five were untraded. All three Big Caps were up.

Ellex was the best, up four cents or 7.2 percent to 59.5 cents with 85,925 shares traded. Uscom climbed 6.25 percent; Oncosil and Orthocell were up more than five percent; Nanosonics rose 2.1 percent; Cochlear, CSL, Dimerix, Resmed and Volpara were up more than one percent; with Clinuvel, Compumedics, Neuren, Sirtex and Starpharma up by less than one percent.

Airxpanders led the falls, down 1.5 cents or 13.0 percent to 10 cents with 1.2 million shares traded. Factor lost 9.3 percent; Immutep shed 8.1 percent; Prescient was down 7.1 percent; Cynata retreated 5.05 percent; Impedimed, LBT and Prana fell more than four percent; Actinogen and Osprey were down more than three percent; Bionomics, Mesoblast, Opthea, Optiscan, Pro Medicus, Telix and Universal Biosensors shed two percent or more; with Medical Developments and Polynovo down less than one percent.

AVITA MEDICAL

Avita says it has commitments to raise \$16,023,783 at five cents a share, in a placement for the US launch of its Recell burn treatment device.

Avita said the placement price was a 3.8 percent discount to the closing price on June 1, 2018 and a 6.3 percent discount to the 30-day volume weighted average price.

The company said that the placement to institutional and sophisticated investors would be in two tranches, with the first tranche of \$12,773,783 expected to settle on June 12, 2018, and the second tranche of \$3,250,000 subject to shareholder approval.

Avita chief executive officer Dr Michael Perry said the proceeds would prepare the company for its US Recell launch "including establishment of our marketing and sales team, scale-up of manufacturing capabilities and expansion of research and development in areas such as paediatric burns, aesthetics and chronic wounds".

Avita said the US Food and Drug Administration review was expected by October 2018.

The company said the placement's sole lead manager was Bell Potter.

Avita was unchanged at 5.2 cents.

ORTHOCELL

Orthocell says interim results of the first 10 patients from its study of Cellgro for tendon regeneration show it has the ability to guide tendon healing in the shoulder.

Orthocell said patients who had previously suffered full thickness tears of the rotator cuff tendon within the shoulder showed a reduction in pain and an improvement in function and quality of life observed at six and 12 months post-treatment.

The company said the results showed no adverse side effects and that no tendon re-tears requiring surgery followed the treatment.

Orthocell chief executive officer Paul Anderson said the study results "show a safety and tolerability profile with reductions in pain, improvement in function and quality of life".

"Celgro is proving to be a breakthrough soft tissue reconstruction platform technology with positive data announced now, in both bone and tendon applications," Mr Anderson said.

Orthocell said the study of its collagen device for soft tissue repair was performed by its chief scientific officer Prof Ming Hao Zheng and Prof Allan Wang at the St John of God Subiaco Hospital.

Orthocell began the trial in 2015 and Mr Anderson told Biotech Daily that he expected to complete recruitment by April with results by July 2019 (BD: Dec 16, 2015).

Orthocell was up two cents or 5.7 percent to 37 cents.

ZELDA THERAPEUTICS

Zelda says that increasing doses of pure tetrahydrocannabinol or pure cannabidiol reduces brain cancer cell viability in cell-based assays.

Zelda said the paediatric medullo-blastoma brain cancer research project showed that high doses of tetrahydrocannabinol (THC) and cannabidiol (CBD) in combination with the chemotherapy agent cyclophosphamide increased the anti-proliferative effect in cancer.

The company said the research project was a collaboration with the Perth-based Telethon Kids Institute and focused on the pre-clinical testing of Zelda's products on paediatric medulloblastoma cell lines.

Zelda said the project would be confined to pre-clinical research accessing validated cell and animal models for the studies and consisted of a series of experiments designed to produce a data pack to be used as the basis for future clinical trials.

Zelda fell half a cent or 4.35 percent to 11 cents with 1.7 million shares traded.

NANOSONICS

Nanosonics says the first large-scale US national survey of ultrasound probe use and decontamination practice shows significant non-compliance with current guidelines. Nanosonics said the survey, published in the American Journal of Infection Control, confirmed the expansion of ultrasound to most hospital departments, with “a wide range of probe use and reprocessing practice and significant non-compliance with guidelines”. The company said that the study “concluded that the findings underscore the urgent need to review policies and practice to ensure best practice for patient safety”. Nanosonics has developed and commercialized the Trophon EPR ultrasound probe cleaning system.

Nanosonics said that the study, titled ‘Ultrasound probe use and reprocessing: Results from a national survey among US infection preventionists’ was available at:

<https://www.sciencedirect.com/science/article/pii/S0196655318302554>.

The company said that during certain ultrasound procedures, both intracavity and surface probes could become contaminated with clinically relevant pathogens and a failure to comply with required reprocessing procedures put patients at risk of cross contamination. Nanosonics said that US guidelines recommend that for ultrasound probes that enter or contact sterile tissues or the blood system, “sterilization or high-level disinfection and use of a sterile sheath is required”.

The company said the survey identified “relatively high” compliance for reprocessing intracavity semi-critical transducers, such as those used internally in trans-vaginal or transrectal ultrasound, but for surface ultrasound probes, compliance was low.

Nanosonics said that for semi-critical procedures, such as ultrasound guided tissue sampling procedures such as biopsies, the survey found 41 percent non-compliance with the required decontamination practice, while ultrasound guided delivery of drugs or therapeutics, such as nerve blocks or intra-articular injections, had a 61 percent non-compliance rate and for ultrasound probe use across non-intact skin including burns, skin breakdown or partially healed wounds, non-compliance was 45 percent.

Survey co-author, the University of Louisville’s Prof Ruth Carrico said the survey showed “some alarming results”.

“We identified a number of variations in current practice that involve reprocessing of ultrasound probes ... [which] conflict with existing evidence-based recommendations and represent risks to the safety of patients,” Prof Carrico said.

“There are areas of procedure awareness that need to be addressed, such as the application of high level disinfection to all surface ultrasound transducers used in invasive procedures,” Prof Carrico said.

Nanosonics chief executive officer Michael Kavanagh said the survey highlighted the requirement for education to ensure the infection prevention community and clinical practitioners were aware of the cross-contamination risks associated with semi-critical surface ultrasound probes used across a wide range of ultrasound procedures.

“It is important that the healthcare community is kept up to date with latest practice as well as the evidenced based guidelines which require high level disinfection for all semi-critical surface probes,” Mr Kavanagh said.

“The Trophon device is designed for both intracavity as well as surface probes and is validated for use with over 1,000 different probes across all major ultrasound companies,” Mr Kavanagh said.

“Using Trophon for all semi-critical probes represents a large opportunity for Nanosonics and the outcomes of this study helps bring the necessary attention to this important topic,” Mr Kavanagh said.

Nanosonics was up six cents or 2.1 percent to \$2.92 with 2.3 million shares traded.

LBT INNOVATIONS

LBT says that following a strategic review it will not go ahead with a \$2,513,000 Federal Government grant for its Woundvue prototype device.

In December, LBT said it had been awarded the grant by the Department of Innovation Industry and Science competitive Cooperative Research Centre (CRC) as part of a joint application with the University of Melbourne and Planet Innovation which were collaborating on the development of the Woundvue device (BD: Dec 7, 2017).

Today, the company said that grant was contingent on a forecast spending of up to \$10.9 million over three-years and it had decided not to proceed, but would consider co-developing with a commercial partner and licencing the technology.

LBT said it had spent about \$1 million on the Woundvue program, which had resulted in a prototype device in use at the Central Adelaide Local Health Network and a body of intellectual property owned by the company.

The company said that priorities had been identified and approved by the board along with funding requirements, the most critical of which was the commercialization of its automated plate assessment system (APAS) Independence instrument to deliver revenue and lead to broader market adoption.

LBT said that a secondary priority was to expand the APAS Independence to broader sectors such as agriculture.

LBT chief executive officer Brent Barnes said the company's focus "remains wholly on commercializing APAS to generate sales, cash flow and confidence in our business model".

"The Woundvue development program demonstrates our [artificial intelligence] platform technology can be extended which is a major asset to the company and our shareholders," Mr Barnes said.

"For now we are focused on achieving an immediate or near term commercial payback and being strategic about how we deploy our resources and further expand our product portfolio," Mr Barnes said.

LBT fell half a cent or 4.55 percent to 10.5 cents with 1.9 million shares traded.

ATOMO DIAGNOSTICS

Atomo says Owen Mumford has bought exclusive rights for commercialization of the company's range of in-vitro rapid HIV diagnostics under its Simplitude brand.

Atomo said that the Woodstock, Oxfordshire Owen Mumford's Simplitude diagnostic, would be available in Europe in 2018 and could detect the presence or absence of HIV antibodies in a single drop of blood obtained from a fingertip and the result returned within minutes.

The company said the partnership was focused on professional use testing in Europe and would explore options to extend the agreement to cover HIV self-testing.

Atomo said that while rates of HIV infection in Europe were comparatively lower than in African or Commonwealth of Independent States countries, rates of detection were "concerning" with one in six HIV cases undiagnosed and 47 percent diagnosed late.

Atomo chief executive officer John Kelly said the partnership "offers significant mutual benefits and, by leveraging Owen Mumford's established sales network, will support the roll-out of Atomo's HIV test devices in developed healthcare markets".

"Our companies have already formed a close working relationship and we are hoping to extend the scope and nature of our collaboration in the months ahead to further support the growth plans of both companies," Mr Kelly said.

Atomo is a private company.

BOTANIX PHARMACEUTICALS

Botanix says its 37-patient trial of its synthetic cannabidiol BTX1204 for atopic dermatitis or eczema showed it was safe after four weeks of treatment and had efficacy.

Botanix said the placebo-controlled, phase Ib trial randomized 25 patients to the treatment group and 12 patients to the placebo group, with 32 patients completing the study.

The company said there were no significant adverse effects or reports of skin irritation during the study.

Botanix said that after four weeks of treatment 35 percent of patients on BTX1204 had achieved treatment success, compared to 18 percent from the placebo group.

The company did not provide the specific number of patients achieving treatment success.

Botanix said the study was not large enough to show statistical differences in efficacy, but improvements in inflammation, exudation and lichenification were observed in patients treated with BTX1204 compared to the placebo group.

Botanix executive director Matt Callahan said the “results show that BTX1204 was twice as effective as the vehicle in providing a clinical meaningful outcome”.

“BTX1204’s efficacy profile is in line with existing topical products whose treatment success rates are typically between 25 to 35 percent,” Mr Callahan said.

“This combined with the excellent safety profile demonstrated to date underlines the potential for BTX1204 to be a very safe and exciting new treatment for the millions of patients who suffer from this disease,” Mr Callahan said.

Botanix said it would consider partnering, licencing or a phase II trial for BTX1204.

Botanix fell 3.5 cents or 19.4 percent to 14.5 cents with 22.8 million shares traded.

CANN GROUP

Cann says it will expand its research and development operations with La Trobe University.

Cann said that a memorandum of understanding with La Trobe was a precursor to a potential strategic agreement to “enhance its capabilities across research, teaching and knowledge related to the medicinal cannabis industry”.

The company said that its headquarters was at La Trobe University and chief executive officer Peter Crock said the “deeper relationship” would strengthen capabilities in plant genetics, breeding, cultivation, extraction and analysis, while building a pipeline for trials.

La Trobe University research deputy vice-chancellor Prof Keith Nugent said that his university’s “research strengths and capabilities in agricultural and biomedical sciences complement those of Cann Group”.

“Our research into medicinal cannabis may help develop a body of evidence that could lead to treatments for a range of medical conditions,” Prof Nugent said.

Cann fell 10 cents or 3.2 percent to \$3.00 with 468,882 shares traded.

ESENSE LAB

Esense says it has developed vaporizer electronic liquids with the aroma of various cannabis strains, infused with cannabis concentrate.

Esense said the cannabis electronic liquid, or e-liquids, were formulated using natural propylene glycol and vegetable glycerine and reinforced with derived cannabis-like terpenes of strains.

Esense said the formulations copied the flavor and aroma of popular cannabis strains such as Granddaddy Purple, Gorllia Glue and OG-Kush.

Esense fell 0.1 cents or 1.4 percent to seven cents.

[RESAPP HEALTH](#)

Resapp says the US Patent and Trademark Office has allowed a patent covering its cough sound-based audio system for diagnosing respiratory diseases. Resapp said that the patent, titled 'Method and Apparatus for Processing Patient Sounds' provided intellectual property coverage until March 2032.

The company said the patent covered the use of a cough sound-based audio processing pipeline for diagnosing respiratory disease and protected a component of its Resappdx smartphone application diagnostic for acute respiratory disease.

The company said the patent was owned by the University of Queensland and was licenced exclusively to Resapp for the lifetime of the patent.

Resapp said it had filed or had exclusive licence to three other patent applications which were at either provisional or patent cooperation treaty application stage.

Resapp fell half a cent or 3.45 percent to 14 cents.

[ADMEDUS](#)

Admedus has requested a trading halt "pending an announcement regarding the termination of a material supply agreement for its infusion business".

Trading will resume on June 8, 2018 or on an earlier announcement.

Admedus last traded at 27.5 cents.

[NUHEARA](#)

Nuheara has requested a trading halt "pending the release of an announcement regarding a capital raising".

Trading will resume on June 8, 2018 or on an earlier announcement.

Nuheara last traded at 10.5 cents.

[STARPHARMA](#)

FIL Limited says it has reduced its substantial holding in Starpharma from 29,022,710 shares (7.91%) to 25,549,892 shares (6.90%).

The Bermuda-based FIL said it bought, sold and "transitioned" shares between June 9, 2016, and June 1, 2018 at prices ranging from 65 cents to \$1.64.

Starpharma was up half a cent or 0.4 percent to \$1.18.

[CLARITY PHARMACEUTICALS](#)

Clarity says it has appointed Michelle Parker as head of clinical operations.

Clarity said Ms Parker had worked in the nuclear medicine and pharmaceutical industries for the last 20 years, most recently at Novartis as the head of international clinical research operations.

The company said Ms Parker held a Bachelor of Science in Applied Science in Medical Radiation Technology from the University of Sydney.

Clarity is a public unlisted company.

ALCHEMIA

Alchemia says it has appointed Cameron Petricevic as a non-executive director, replacing David Lamm, effective from today.

Alchemia said Mr Petricevic had worked in the finance industry for more than 15 years, including at Acorn Capital and AXA Asia Pacific, primarily in the areas of investments, valuations and corporate finance.

The company said that Mr Petricevic held a Bachelor of Commerce and a Bachelor of Engineering from the University of Melbourne.

Alchemia was unchanged at 1.2 cents.