



Biotech Daily

Thursday July 25, 2019

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH EVEN: OPTISCAN, ORTHOCELL UP 9%;
- COMPUMEDICS DOWN 11%**
- * **ORTHOCELL: 'CELGRO REPAIRS RAT NERVES BETTER THAN SUTURES'**
- * **MESOBLAST: 'ARTICLE SUPPORTS MPCs FOR HEART FAILURE'**
- * **RACE TREATS 1st BISANTRENE AML PATIENT**
- * **PHARMAXIS REVENUE UP 29% TO \$12m**
- * **GENETIC SIGNATURES RECEIPTS UP 49% TO \$4.8m**
- * **REDHILL H1 REVENUE DOWN 31% TO \$4.7m**
- * **UNIVERSAL BIO H1 REVENUE DOWN 71% TO \$4m**
- * **CRESO: 1 QUARTER CASH, AWAITING \$122m PHARMACIELO SALE**
- * **IMAGION RECEIVES \$2m R&D TAX INCENTIVE**
- * **ALTHEA RAISING \$30m FOR CANADA'S PEAK MARIJUANA PROCESSING**
- * **BOD: 220 MEDICAL MARIJUANA SCRIPTS IN 2 MONTHS**
- * **AIRXPANDERS FILES LIQUIDATION WITH US SEC**
- * **MICRO-X REQUESTS CLEANSING NOTICE TRADING HALT**
- * **RESPIRI REQUESTS CAPITAL RAISING TRADING HALT**
- * **BENITEC BELOW NASDAQ \$US1 BID RULE**

MARKET REPORT

The Australian stock market was up 0.61 percent on Thursday July 25, 2019, with the ASX200 up 41.3 points to 6,818.0 points. Seventeen of the Biotech Daily Top 40 stocks were up, 18 fell and five traded unchanged. All three Big Caps were up.

Optiscan and Orthocell were equal best, up 8.9 percent to 4.9 cents and 49 cents respectively, with 868,140 shares and 7.65 million shares traded, respectively. Alterity climbed 7.4 percent; Immutep, Imugene and LBT improved four percent or more; Antisense, CSL, Mesoblast and Opthea rose more than two percent; Cochlear, Cynata, Nanosonics, Neuren, Osprey, Pro Medicus, Proteomics, Resmed and Universal Biosensors were up more than one percent; with Telix up 0.3 percent.

Compumedics led the falls, down 8.5 cents or 10.7 percent to 71 cents, with 197,984 shares traded. Amplia and Benitec lost more than seven percent; Actinogen was down 5.3 percent; Dimerix, Genetic Signatures and Patrys fell more than four percent; Cyclopharm, Resonance and Uscom were down more than three percent; Ellex, Prescient and Volpara shed more than two percent; Kazia and Medical Developments were down more than one percent; with Clinuvel, Paradigm and Starpharma down by less than one percent.

ORTHOCELL

Orthocell says its preclinical study of 30 rats has shown that its collagen medical device Celgro restores severed peripheral nerves better than direct suturing.

Orthocell said it compared motor and sensory outcomes for rats in a control group, a direct suturing group and a Celgro repair group.

The company said the nerve ends of rats treated with Celgro maintained alignment during reconnection and the nerves grown were indistinguishable from normal nerves.

Orthocell said nerves repaired with Celgro transmitted electrical impulses 30 percent better than stitching with a corresponding improvement in muscle function.

The company said nerves returned to normal sensory function two to three weeks faster than the suture repair method.

Orthocell said Celgro supported earlier recovery, reduced surgery time and reduced the risk of additional trauma through the use of sutures.

The company said that suturing caused scarring and fibrosis, which impeded nerve growth and led to disordered nerve alignment.

In May, Orthocell said the first four patients in a 20-patient Celgro nerve regeneration trial regained muscle function and sensation in affected limbs at 24 months (BD: May 8, 2019).

Orthocell managing-director Paul Anderson said the company was “thrilled with the animal study results, indicating Celgro facilitates high quality nerve repair”.

“The results reinforce the initial patient outcomes previously reported from our current human clinical study demonstrating return of sensation and muscle function in affected limbs following Celgro nerve regeneration treatment,” Mr Anderson said.

“Restoring normal nerve structure is critical for regaining mobility, function and quality of life,” Mr Anderson said.

Orthocell was up four cents or 8.9 percent to 49 cents with 7.65 million shares traded.

MESOBLAST

Mesoblast says that a research article supports its use of mesenchymal precursor cells (MPCs) as an “immunotherapy in patients with advanced chronic heart failure”.

Mesoblast said that the article reported that cardiac inflammation drove heart failure progression and concluded that based on pre-clinical and phase II clinical data there was “a biologic rationale for the use of [its] MPCs in targeting this inflammatory process in order to improve heart failure outcomes”.

The research article, titled ‘Phase III Dream-HF Trial of Mesenchymal Precursor Cells in Chronic Heart Failure; A Review of Biological Plausibility and Implementation of Flexible Clinical Trial Design’ was published in Circulation Research, with an abstract available at: <https://www.ahajournals.org/doi/10.1161/CIRCRESAHA.119.314951>.

The research said it aimed “to provide lessons learned from the ongoing Dream-HF trial that relate to biological plausibility and flexible clinical trial design and are potentially applicable to other development programs ... for advanced cardiovascular disease”.

Mesoblast said that based on existing preclinical and phase II trial data of cardiac inflammation and heart failure, there was “a biologic rationale for the use of Mesoblast’s MPCs in targeting this inflammatory process in order to improve heart failure outcomes”.

In February, the company said the last of 566 congestive heart failure patients had been dosed in its phase III trial of Revascor, formerly known as MPC-150-IM, and the trial would be completed when it met sufficient primary endpoint events, likely within 12 months (BD: Feb 19, 2019).

Mesoblast was up 3.5 cents or 2.35 percent to \$1.525 with 702,118 shares traded.

RACE ONCOLOGY

Race says it has treated the first of 12 patients in its phase II trial of Bisantrene for acute myeloid leukemia at the Israel-based Sheba Medical Centre.

In May, Race said the investigator-initiated trial for relapsed and/or refractory acute myeloid leukemia (AML) had been approved by Israel's Ministry of Health and would be led by Tel Aviv University professor of medicine and Sheba haematology director Prof Arnon Nagler (BD: May 14, 2019).

Today, the company said the patient had been recruited and had completed a seven-day course of Bisantrene without complications.

Race chief executive officer Peter Molloy said treating the patient was "a major milestone for Race, because it's the first treatment with Bisantrene since the drug disappeared more than 25 years ago".

In 2015, when the company began the Bisantrene program, Mr Molloy told Biotech Daily that Bisantrene was a phase II/III drug previously trialled in 44 clinical studies and on more than 2,000 patients, which showed it did not have the cardiac toxicities of other anthracycline drugs used as chemotherapy agents for cancer (BD: Aug 27, 2015).

Mr Molloy said at that time that Bisantrene had been approved in France for acute myeloid leukaemia but never launched, because it was effectively "lost" in a string of pharmaceutical company mergers including the Lederle-Immunex merger, then sold to Wyeth and then to Pfizer, with \$US100 million spent on it by Lederle and the US National Cancer Institute.

Race was up 1.7 cents or 39.5 percent to six cents with two million shares traded.

PHARMAXIS

Pharmaxis says revenue for the year to June 30, 2019 is up 28.5 percent to \$12,171,000 compared to the previous year, excluding a \$42 million licence payment.

Pharmaxis said that in the 12 months to June 30, 2018 total revenue was \$8,703,000 not including payments totaling \$42,130,000 from Boehringer Ingelheim for the rights to drug candidate BI 1467335, formerly PXS-4728A.

In its Appendix 4C, the company said that receipts from customers from the sales of Bronchitol and Aridol for the three months to June 30, 2019 were up 25.1 percent to \$2,390,000 compared to the previous corresponding period, with a cash burn of \$3,404,000 at June 30.

Pharmaxis said it had cash and cash equivalents of \$31,124,000 at June 30, with an expected outflow of \$8,370,000 for the three months to September 30, 2019.

Pharmaxis was unchanged at 23 cents.

GENETIC SIGNATURES

Genetic Signatures says that receipts from customers for the year to June 30, 2019 were up 48.6 percent to \$4,754,000 compared to the previous year.

Genetic Signatures said receipts from customers for its respiratory pathogen detection kits for the three months to June 30, 2019 rose 146.3 percent to \$1,256,000 compared to the previous corresponding period, with a cash burn of \$1,209,000 for the period.

The company said it had cash and cash equivalents at June 30 of \$6,311,000 with an expected outflow of \$2,543,000 for the three months to September 30, 2019.

Genetic Signatures fell five cents or 4.2 percent to \$1.15.

REDHILL BIOPHARMA

Redhill says its revenue for the six months to June 30, 2019 is down 31.2 percent to US\$3,300,000 (\$A4,728,656) with net loss after tax down 1.3 percent to US\$20,778,000 (\$29,771,977).

Redhill said the income was from US sales of its Donnatal for irritable bowel syndrome, Mytesi for diarrhoea in HIV patients on anti-retroviral drugs, and the Enteragam food supplement for diarrhoea, with a planned US launch of Talicia, formerly RHB-105 and previously Heliconda, for Helicobacter pylori infection.

The company said that loss per share fell 30 percent to 7.0 US cents (10 Australian cents).

In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).

On the Nasdaq, Redhill fell 10 US cents (14.3 Australian cents) or 1.37 percent to US\$7.19 (\$A10.30) with 116,632 shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says that revenue for the six months to June 30, 2019 was down 70.5 percent to \$3,977,357, not including a \$44 million payment from Lifescan.

Universal Biosensors said that revenue from products was up 154 percent to \$2,294,362 from sales of its Xprecia Stride coagulation analyzer test strips to Siemens.

The company said that revenue from services was up 170 percent \$1,518,418 compared to the previous corresponding period.

Universal Biosensors said quarterly service fees fell to \$164,577, with Johnson & Johnson subsidiary Lifescan no longer buying its Onetouch Verio blood glucose strips.

In February, the company said it had received \$US31,503,880 (\$A44,036,123) from Johnson & Johnson's Lifescan as a buy-out from the obligation to pay quarterly service fees to Universal Biosensors for its blood sugar test strips (BD: Feb 18, 2019).

The company said it spent \$7,800,006 for the six months to June 30, 2019, down 33.3 percent compared to the previous corresponding period.

The company said that net tangible asset backing per share was up 271.4 percent to 26 cents a share, with diluted loss per share was 0.2 cents compared to the previous period's 0.0 cents.

Universal Biosensors said that it held cash and cash equivalents of \$50,553,981 at June 30, 2019, compared to \$31,138,000 at December 31, 2017.

Universal Biosensors was up 0.25 cents or one percent to 24.25 cents.

CRESO PHARMA

Creso says it has one quarter of cash, but is expecting to be acquired by the Vancouver, British Columbia-based Pharmaciolo.

Creso said it had cash and cash equivalents at June 30, 2019 of \$3,580,000 with an expected outflow of \$3,618,000 for the three months to September 30, 2019.

Last month, the company said it would be acquired by Pharmaciolo for \$122 million, and would receive a \$C3,500,000 (\$A3,825,140) secured bridging loan in advance for general working capital, repayable by December 31, 2019 or within four months if the scheme was not approved (BD: Jun 7, 2019).

Creso was up half a cent or 1.25 percent to 40.5 cents.

IMAGION BIOSYSTEMS

Imagion says it has received \$2,061,918 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Imagion said the rebate related to research and development expenditure for the year to December 31, 2018.

Imagion was up 0.3 cents or 6.8 percent to 4.7 cents with 6.7 million shares traded.

ALTHEA GROUP HOLDINGS

Althea says it has commitments to raise \$30 million at \$1.00 a share in a placement to fund the acquisition of Canada manufacturing company Peak Processing Solutions.

Althea said it had commitments from new and existing institutional shareholders for the placement to acquire the Tecumseh, Ontario-based Peak Processing.

The company said Peak was established to extract and manufacture marijuana infused foods, drinks, food additives and cosmetics, for which it had applied for a large-scale cannabis processor licence.

Althea said it would provide \$C4.1 million (\$A4,5 million) in cash and 25,851,846 shares on completion of the acquisition to former Peak director Greg Battersby and employee shareholders, in three stages, subject to shareholder approval.

The company said that initially it would grant 1,331,384 shares to employee shareholders and 5,502,455 shares to former Peak director Gregg Battersby.

Althea said it would grant 5,705,402 shares on receipt of a cannabis processor licence, 5,705,402 shares for reaching \$C7 million revenue and \$C2 million on further milestones.

The company said it launched its first "cannabis destination clinic" in Belgravia, London would open two more by October, and had a UK import licence and patient assessments for patient access to sell marijuana products through Boots Pharmacy's 2,500 outlets.

Althea fell 3.5 cents or 2.9 percent to \$1.16 with 4.1 million shares traded.

BOD AUSTRALIA

Bod says it has filled 220 prescriptions for its Medicabillis marijuana extract for pain, neurological disorders, gastrointestinal diseases and anxiety in June and July 2019.

Bod said prescriptions were up from 55 from January to May, with 161 prescriptions in July, a 273 percent increase over June 2019, including prescriptions for pain symptoms, neurological conditions, stress and anxiety and gastrointestinal diseases.

Bod said the growth due to its ongoing doctor education program and Burleigh Heads Cannabis agreement with Cannabis Doctors Australia (BD: Jun 21, 2019).

Bod was up 6.5 cents or 11.6 percent to 62.5 cents with 3.5 million shares traded.

AIRXPANDERS

Airxpanders says it has filed a notice with the US Securities and Exchange Commission confirming its bankruptcy and liquidation (BD: Jul 17, 2019).

Airxpanders said it had advised the ASX of its intention to be removed from the ASX official list, which was expected by the end of September 2019.

The company said it had filed for relief under the provisions of Chapter 7 of Title 11 of the US bankruptcy code, a trustee would be appointed and it would be liquidated.

The company said chairman Barry Cheskin, chief executive officer Frank Grillo and directors Dennis Condon, Gregory Lichtwardt and Elizabeth Hammack had resigned.

Airxpanders was in an extended suspension and last traded at 3.5 cents.

[MICRO-X](#)

Micro-X says it has requested a trading halt “pending an application to the Federal Court of Australia to seek orders after it failed to give the ASX a cleansing notice”.

Micro-X said it inadvertently failed to provide the cleansing notice for shares issued on June 4 and 14 and July 10, 2019.

Trading will resume on July 29, 2019 or on an earlier announcement.

Micro-X last traded at 32.5 cents.

[RESPIRI](#)

Respiri has requested a trading halt “pending an announcement in relation to proposed capital raising initiatives”.

Trading will resume on July 29, 2019 or on an earlier announcement.

Respiri last traded at 12 cents.

[BENITEC BIOPHARMA](#)

Benitec says it has received a non-compliance letter from the Nasdaq requiring it to ensure its share price is above \$US1.00 within 180 days.

Benitec said that the Nasdaq had informed the company that its American depository share price had been below the \$US1.00 minimum for 30 consecutive business days and it had 180 days to January 18, 2020 to regain compliance, with the minimum bid price at or above \$US1.00 for 10 consecutive business days.

The company said that each American depository share represented 20 ASX shares.

Benitec said the deficiency notice did not immediately affect its Nasdaq listing and only applied to the Nasdaq and not the shares trading on the ASX.

Benitec fell 0.4 cents or 7.8 percent to 4.7 cents.