



# Biotech Daily

Monday August 26, 2019

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: USCOM UP 9.5%; ANTISENSE DOWN 17%**
- \* **ADMEDUS H1 REVENUE DOWN 16% TO \$11m, LOSS UP 3% TO \$12m**
- \* **MACH7 REVENUE UP 8% TO \$9.3m, LOSS UP 43% TO \$7m**
- \* **ACRUX REVENUE DOWN 64% TO \$1.2m, LOSS DOWN 41% TO \$8.3m**
- \* **INVITROCUE RAISES \$966k**
- \* **EXOPHARM STARTS 'PLEXOVAL' EXOSOME WOUND HEALING TRIAL**
- \* **CE MARK RENEWAL FOR 3 USCOM SPIROSONIC DEVICES**
- \* **ANTISENSE: ACROMEGALY EUROPE ACCESS PROGRAM ON HOLD**
- \* **NUHEARA TO ASX: 'NHS RECATEGORIZATION NOT MATERIAL'**
- \* **RECCE: 500% PRODUCTION INCREASE**
- \* **CANN GLOBAL, PHARMOCANN MARIJUANA FOOD, COSMETICS DEAL**
- \* **PHARMAUST RECEIVES MONEPANTEL DOG TRIAL TABLETS**
- \* **G MEDICAL DROPS \$25m NASDAQ IPO FOR OTCQB LISTING**
- \* **NOXOPHARM RECEIVES \$3.7m FEDERAL R&D TAX INCENTIVE**
- \* **CRYSTAL AMBER FUND TAKES 75% OF GI DYNAMICS**
- \* **MATT CALLAHAN, STONE RIDGE, SRV TRANSFER BELOW 5% IN ORTHOCELL**

## MARKET REPORT

The Australian stock market fell 1.27 percent on Monday August 26, with the ASX200 down 83.0 points to 6,440.1 points. Eight of the Biotech Daily Top 40 stocks were up, 26 fell, four traded unchanged and two were untraded. All three Big Caps fell.

Uscom was the best, up one cent or 9.5 percent to 11.5 cents, with 68,967 shares traded. Pro Medicus climbed 5.7 percent; Kazia was up 4.2 percent; Dimerix improved 3.3 percent; Polynovo rose 2.85 percent; Cyclopharm and Neuren were up more than one percent; with Compumedics up 0.7 percent.

Antisense led the falls, down 0.9 cents or 17.0 percent to 4.4 cents with 4.7 million shares traded. Resonance lost 12.5 percent; LBT fell 9.1 percent; Imugene shed 8.7 percent; Clinuvel fell 7.1 percent; Ellex, Next Science, Orthocell and Pharmaxis were down more than five percent; Oncosil, Patrys and Starpharma fell more than four percent; Cochlear, Cynata and Impedimed lost more than three percent; Amplia, Opthea, Paradigm and Resmed shed more than two percent; Avita, CSL, Osprey, Proteomics and Telix were down more than one percent; with Genetic Signatures, Medical Developments, Mesoblast, Nanosonics and Volpara down by less than one percent.

## ADMEDUS

Admedus says that revenue for the six months to June 30, 2019, was down 16.4 percent to \$10,702,248 with net loss after tax up 3.2 percent to \$11,916,566.

Admedus said the revenue came from sales of its Adapt Cardioceal treated bovine tissue for heart repair and other indications, which generated \$5,713,811 in revenue, along with its hospital supply infusion business which recorded \$4,988,437 in revenue, which fell from last year following the partial sale to Melbourne's BTC Health for \$6.3 million in May (BD: May 31, 2019).

The company said "employee benefits" were down 6.3 percent to \$11,425,469, with research and development up 4.0 percent to \$1,639,736 for the six months to June 30. The company said its total current liabilities were down 28.8 percent to \$9,305,444 compared to the previous corresponding period.

Admedus said that net tangible asset backing per share fell 26.3 percent to 1.4 cents, with basic loss per share up 50.6 percent to 1.96 cents.

The company said that it had cash and cash equivalents of \$4,886,541 at June 30, 2019, compared to \$12,036,301 at December 31, 2018 and \$4,425,861 at June 30, 2018.

Earlier this month, the company requested a sixth extension to its voluntary suspension to finalize its re-capitalization plan and last week, the ASX suspended Admedus for failing to pay the annual listing fee (BD: Aug 5, 22, 2019).

Admedus last traded at six cents.

## MACH7 TECHNOLOGIES

Mach7 says that revenue for the year to June 30, 2019 was up 8.1 percent to \$9,347,146, with net loss after tax up 42.5 percent to \$7,058,729.

Mach7 said that the revenue was a combination of medical imaging licence fees, annual support fees, professional service fees, and interest.

The company said that in 2018-'19 it "executed 24 new sales order contracts with a record total contract revenue value of \$21 million and 62 percent growth on 2017-'18", with six new customers, including Hospital Authority Hong Kong, Children's Hospital of Alabama, Sampson Regional Medical Center, Loyola University Health System and Mississippi State University College of Veterinary Medicine.

The company said that its net tangible asset backing per share fell 50.0 percent to 1.0 cent, with diluted loss per share up 30.8 percent to 5.1 cents and it had cash and cash equivalents of \$2,267,448 at June 30, 2019 compared to \$2,504,587 at June 30, 2018.

Mach7 fell 3.5 cents or 4.2 percent to 79 cents.

## ACRUX

Acrux says that revenue for the year to June 30, 2019 fell 64.0 percent to \$1,210,000 with a net loss after tax down 41.3 percent to \$8,325,000.

Acrux said that royalty revenue from its Axiron generic testosterone product had reduced to nil, "reflecting the termination of the Axiron licencing agreement".

The company said it received royalty revenue of \$581,000 for its Lenzetto estradiol spray for menopause symptoms and interest on cash deposits of \$579,000.

Acrux said its diluted loss per share fell 41.3 percent for five cents, with net tangible asset backing per ordinary share down 27.8 percent to 13.0 cents.

The company said it had the company had \$18,152,000 in cash and cash equivalents at June 30, 2019, compared to \$28,470,000 at June 30, 2018.

Acrux was up one cent or 5.7 percent to 18.5 cents.

## INVITROCUE

In an Appendix 3B and cleansing notice, Invitrocue says it has raised \$965,800 through a private placement of 16,096,667 new shares at six cents each.

Invitrocue said it had allotted 3,219,334 unlisted options exercisable at nine cents each by August 23, 2024.

Last week, the ASX said it had suspended Invitrocue for failing to pay the annual listing fee, and the company would be removed if the fee was not paid by the close of trading on Wednesday August 28, 2019.

Invitrocue was suspended at six cents.

## EXOPHARM

Exopharm says it has begun its 20-patient, open-label, single dose phase I trial of its exosome product Plexaris for wound healing.

Exopharm said the 'Plexoval' trial, at the Royal Melbourne Hospital and the Australian Red Cross Blood Service, would be facilitated by the Melbourne-based Accelagen contract research organisation.

The company said the trial would investigate "the safety, tolerability and biological activity of platelet-derived extracellular vesicles for the augmentation of wound healing".

Exopharm said the trial would also assess wound closure, wound strength, wound histology and scar formation.

The company said the patients would be assessed over 42-days and be divided into two cohorts, with cohort one involving up to 15 patients, and cohort two involving up to five patients.

Exopharm founding chief executive officer Dr Ian Dixon told Biotech Daily the doses would be administered by injection into the boundary of undisclosed wounds.

In the media release, Dr Dixon said that "wounds and poor wound healing are medical problems affecting thousands of Australians every year [and] as we age our ability to heal declines and the prevalence of chronic wounds increases," Dr Dixon said.

"Exosomes from platelets have been shown in animal studies to improve wound closure and reduce scarring," Dr Dixon said.

"This human study is looking at whether our Plexaris product might become a useful improved treatment option," Dr Dixon said.

"This Plexoval study positions Exopharm as a leader in the cell-free exosome field of regenerative medicine world-wide," Dr Dixon said.

Exopharm fell half a cent or 1.3 percent to 38 cents.

## USCOM

Uscom says it has Conformité Européenne (CE) mark re-certification for its Spirosonic Flo, Smart and Mobile digital ultrasonic spirometry devices.

Uscom said the re-approval was required following the relocation of Uscom Kft to an expanded facility in Budapest to accommodate an expected increased demand once Chinese certification was received.

The company said that there was an eight-month interruption to manufacturing and sales while the CE certification process was conducted by the European authority, but despite the interruption, Uscom Kft increased total income by 47 percent for the year to June 30, 2019.

Uscom said the digital ultrasonic Spirosonic Air device was undergoing certification.

Uscom was up one cent or 9.5 percent to 11.5 cents.

## ANTISENSE THERAPEUTICS

Antisense says its provision of ATL1103 for acromegaly under a European Union early access program has been put on hold following a request for a further clinical trial.

Antisense said it had a global agreement with early access provider Mytomorrows to provide ATL1103, also referred to as atesidorsen, under the program to acromegaly patients in selected European Union countries.

The company said that labelled and packaged ATL1103 drug product was being stored in the UK for shipment to Mytomorrows in the Netherlands, but so far it has not received Mytomorrows' clearance for importation.

Antisense said that following an external review, requested by Mytomorrows, it was told that due to the ATL1103 material intended for use in the early access program being supplied by a different manufacturer to the one used in the previous phase II trial of ATL1103, it would need to be approved by a European health authority for use in a new clinical trial, to be cleared for the early access program.

"A new clinical trial would require a substantial financial commitment from the company to proceed with the next phase of clinical development for ATL1103," Antisense said.

The company said its focus was on its current phase II trial of ATL1102 for Duchenne's muscular dystrophy at Melbourne's Royal Children Hospital, which was due to complete dosing in November with result expected shortly after.

Antisense said that "circumstances could present in the future where the company has the capacity and justification to continue to invest in the further clinical development of ATL1103, including activation of an [early access program]".

The company said that it had interest from European experts in the use of ATL1103 for patients uncontrolled on existing therapy and in testing ATL1103 with pegvisomant to exploit potential synergistic clinical benefits, and it was exploring opportunities to provide ATL1103 drug product to experts to generate supportive clinical data, as well as pursuing the potential out-licencing of ATL1103.

Antisense fell 0.9 cents or 17.0 percent to 4.4 cents with 4.7 million shares traded.

## NUHEARA

Nuheara has told the ASX that a recategorization of its products by the UK National Health Service was not material because no value had been placed on the contracts.

The ASX asked Nuheara a series of detailed questions regarding announcements on November 28, 2018 and March 25, 2019, which said that the company's Iqbuds hearing and sound filtering ear buds were the first buds to be placed on the UK National Health Service for adults and children with mild to moderate hearing loss.

Nuheara said in November that it was the first time a smart hearing bud was able to be prescribed alongside traditional hearing aids (BD: Nov 28, 2015).

In March, the company said that the Iqbuds Boost had been recategorized by the UK National Health Service contract from "a hearing aid/accessory" to a niche innovation "hearable" (BD: Mar 25, 2019).

On Friday, Nuheara told the ASX, that "at no point did the company make any announcement at any time regarding the value of the award to the company as it was not the contracting party and was not guaranteed any revenues or orders under the tender award to [distributor] Puretone".

The ASX noted that the company's share price increased 11.4 percent from 7.9 cents on November 27 to 8.8 cents on November 28, 2018 and fell 14.5 percent from 6.9 cents on March 22 to 5.9 cents on March 25, 2019.

Nuheara fell 0.1 cents or 3.6 percent to 2.7 cents with 5.3 million shares traded.

### RECCE PHARMACEUTICALS

Recce says it has increased production by 500 percent of its synthetic antibiotic Recce 327, which has a six-month shelf life at 2.0 to 8.0 degrees Celsius.

Recce said it has received a positive US Food and Drug Administration review of its scaled manufacture and drug quality, which inspected its chemistry, manufacturing, and controls data pack.

The company said it would continue to improve its good manufacturing practice capabilities at its Sydney manufacturing facility using quality controls consistent with guidelines for human clinical purposes.

Recce Chairman Dr John Prendergast said "our current manufacturing capability affords us the potential to achieve excellent economies of scale and reproducibility in terms of future commercial batches".

Recce was up two cents or 9.5 percent to 23 cents.

### CANN GLOBAL (FORMERLY QUEENSLAND BAUXITE)

Cann Global says it has an agreement with Pharmocann to produce and manufacture marijuana-based food additives and cosmetics at Sydney's Bio Health facility.

Cann Global said the agreement, through its wholly-owned subsidiary Medcann, would manufacture the Jezreel, Israel-based Pharmocann's cannabis-based food additives in Australia, which would be marketed under the Cann Global label for distribution in Australia, Asia and other international markets.

Cann Global executive chairperson Pnina Feldman said the company hoped "that Pharmocann's range of cannabis and hemp products will significantly add to our revenues with their amazing formulas for skin care for men and women being prepared for immediate production".

Cann fell 0.6 cents or 20.7 percent to 2.3 cents with 39.1 million shares traded.

### PHARMAUST

Pharmaust says it has received 7,750 good manufacturing practice-grade monepantel tablets for its trial in dogs with B cell lymphoma.

Pharmaust said it expected to begin delivery of the tablets to veterinarians conducting the trial this week.

Pharmaust was up half a cent or 5.3 percent to 9.9 cents with 1.4 million shares traded.

### G (GEVA) MEDICAL

G medical says it will withdraw its Nasdaq registration statement and pursue an Over-The-Counter Quality Exchange second board (OTCQB) listing.

Earlier this year, G Medical said it hoped to raise \$US17,000,000 (\$A24,570,907) and list its American depository shares on the Nasdaq (BD: May 20, 2019).

Today, the company said the "Nasdaq listing, and associated capital raising, was not in the best interest of its shareholders".

G Medical said the OTCQB listing would not dilute existing shares and would not require a capital raising.

G Medical was unchanged at 12 cents.

## GI DYNAMICS

Crystal Amber Fund says it has increased its holding in GI Dynamics from 923,393,919 shares (65.14%) to 1,069,463,354 shares (75.45%).

The Guernsey-based Crystal Amber said between July 4 and August 23, 2019, it acquired shares in several trades with the single largest purchase on July 9 of 438,015 for \$15,331 or 3.5 cents a share, and converted notes to 144,466,319 shares for \$2,950,368 or two cents a share.

Last week, GI Dynamics said it had \$US10 million (\$A14,773,150) in convertible notes and warrants with Crystal Amber Fund to fund trial enrolments and European approval (BD: Aug 22, 2019).

GI Dynamics was up 0.3 cents or 9.1 percent to 3.6 cents.

## NOXOPHARM

Nuheara says it has received \$3.71 million from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Nuheara said that the funds would be used to “finish the 2019 calendar year and provide ongoing liquidity for ... 2020,” including a plan to bring to market its Veyonda, a suppository dosage formulation of anti-cancer drug, idronox.

Noxopharm was unchanged at 41 cents.

## ORTHOCELL

Orthocell director-on-leave Matt Callahan, Stone Ridge Ventures, SRV Custodians and SRV Nominees say they have ceased their substantial holding in Orthocell.

In an Appendix 3Z, Mr Callahan said that through SRV Trust and Shenasaby Super he held 1,081,440 shares and 1,850,000 unlisted options.

In separate substantial shareholder notices, Mr Callahan, Stone Ridge and SRV Custodians said they had transferred their beneficiary holding of 7,570,000 shares.

In a media release, Orthocell said the shares were held by and formally transferred to Australian Super, which held the shares directly.

Orthocell fell 2.5 cents or 5.9 percent to 40 cents.