

Biotech Daily

Tuesday August 31, 2021

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH UP: ACTINOGEN UP 17%; MESOBLAST DOWN 16%
- * ALTHEA RECORD REVENUE UP 128% TO \$11.5m, LOSS UP 1.9% TO \$15m
- * MESOBLAST REVENUE DOWN 77% TO \$10.2m, LOSS UP 27% TO \$135m
- * STEMCELL REVENUE UP 11-FOLD TO \$8.5m, LOSS UP 107% TO \$3m
- * REGENEUS REVENUE UP 325% TO \$7.1m, LOSS TO \$2.15m PROFIT
- * LITTLE GREEN REVENUE UP 218% TO \$7m, LOSS TO \$24.6m PROFIT
- * MEDLAB REVENUE DOWN 3.7% TO \$5.2m, LOSS DOWN 7.9% TO \$12.4m
- * BIOXYNE REVENUE DOWN 6.6% TO \$2.1m, LOSS DOWN 28% TO \$426k
- * INCANNEX REVENUE UP 211% TO \$1.9m, LOSS UP 74% TO \$8.2m
- * PROTEOMICS REVENUE DOWN 8% TO \$1.3m, LOSS UP 64% TO \$2.9m
- * OVENTUS REVENUE UP 160% TO \$1.1m, LOSS DOWN 2.9% TO \$9.8m
- * ORTHOCELL COMPLETES ORTHO-ATI ROTATOR CUFF FOLLOW-UP
- * PHARMAXIS: PXS-6302 FOR BURNS SCARS 'SAFE, WELL-TOLERATED'
- * NEUROSCIENTIFIC: EMTINB 'SIGNIFICANTLY REDUCES MS BIOMARKERS'
- * IMMUTEP: CHINA'S EOC PLANS IMP321, PD-1 TRIAL
- * PHARMAUST: EPICHEM REPAYS LAB EXPANSION LOANS
- * CYNATA: CANADA PATENT FOR CYMERUS STEM CELLS
- * CRESO, RED LIGHT HOLLAND END MERGER; AIMS AT NASDAQ
- * MOVAC FUND 3 BELOW 5% IN AROA
- * EXOPHARM APPOINTS DR JENNIFER KING DIRECTOR

MARKET REPORT

The Australian stock market was up 0.4 percent on Tuesday August 31, 2021, with the ASX200 up 30.4 points to 7,534.9 points. Sixteen of the Biotech Daily Top 40 stocks were up, 14 fell and 10 traded unchanged. All three Big Caps were up.

Actinogen was the best on no news, up 1.6 cents or 17.0 percent to 11 cents, with 6.4 million shares traded, followed by Clinuvel up 10.7 percent to \$37.78 with 541,771, and Imugene through the \$2 billion market capitalization barrier up 9.2 percent to 41.5 cents with 57.0 million shares traded.

Optiscan and Uscom climbed more than seven percent; Dimerix was up 6.1 percent; Pharmaxis improved 4.2 percent; Next Science, Polynovo and Resmed were up more than three percent; Genetic Signatures and Prescient rose more than two percent; Cochlear, Cynata, Immutep, Pro Medicus, Starpharma and Volpara were one percent or more; with CSL up 0.5 percent.

Mesoblast led the falls, down 31.5 cents or 15.9 percent to \$1.665, with 24.7 million shares traded. Medical Developments and Opthea lost more than six percent; Kazia, Oncosil and Resonance fell four percent or more; Alterity, Avita and Impedimed shed more than three percent; Neuren and Orthocell were down more than one percent; with Cyclopharm, Nanosonics and Telix down by less than one percent.

ALTHEA GROUP

Althea says it has record revenue for the year to June 30, 2021, up 128 percent or \$11,540,000, with net loss after tax up 1.9 percent to \$15,056,000.

Althea said revenue came from sales and distribution of pharmaceutical and non-pharmaceutical marijuana-based products.

The company said diluted loss per share was down 5.8 percent to 6.05 cents, with net tangible assets per share down 22.7 percent to 8.68 cents, and it had cash and equivalents of \$6,388,000 at June 30, 2021, compared to \$10,143,000 at June 30, 2020. Althea fell one cent or three percent to 3.2 cents with one million shares traded.

MESOBLAST

Mesoblast says revenue for the year to June 30, 2021 was down 76.8 percent to \$US7,456,000 (\$A10,216,428) with net loss after tax up 26.8 percent to \$US98,811,000 (\$A135,393,701).

Mesoblast said that revenue came from sales of Temcell for acute graft-versus-host treatment in Japan by JCR pharmaceuticals.

The company said that the previous year's revenue included a milestone payment of \$US25,000,000.

Mesoblast said that research and development expenditure fell 5.7 percent to \$US53,012,000, with manufacturing costs up 29.3 percent to \$US32,719,000 and administration costs up 20.5 percent to \$US30,867,000.

The company said diluted loss per share rose 10.8 percent to 16.33 US cents, net tangible asset backing per share was up from 0.97 US cents to 2.67 US cents, and it had cash and cash equivalents of \$US136,881,000 compared to \$US129,328,000 at June 30, 2020. Mesoblast fell 31.5 cents or 15.9 percent to \$1.665 with 24.7 million shares traded.

STEMCELL UNITED

Stemcell says it has record revenue for the year to June 30, 2021, up more than 11-fold to \$8,495,417, with net loss after tax up 106.9 percent to \$2,951,341.

Stemcell said revenue came from its sales of traditional Chinese medicines including Dragon's blood, as well as seaweed and marijuana products.

The company said diluted loss per share was up 81.8 percent to 40.0 cents, with net tangible assets per share down 81.4 percent to 0.11 cents, and it had cash and equivalents of \$5,255,274 at June 30, 2021, compared to \$866,830 at June 30, 2020. Stemcell was up 0.2 cents or 14.3 percent to 1.6 cents with 4.2 million shares traded.

REGENEUS

Regeneus says its revenue for the year to June 30, 2020 was up 324.8 percent to \$7,067,026, with last year's \$1,069,046 net loss after tax turned to a profit of \$2,153,011. Regeneus said the revenue primarily came from \$6.9 million in milestone payments for its Progenza OA (BD: Jul 29, 2021)

The company said that last year's 0.4 cents diluted loss per share was turned to a 0.7 cent diluted earnings per share.

Regeneus said that net tangible asset backing per share was up from negative 0.05 cents to 0.79 cents, and it had cash and cash equivalents of \$3,792,695 at June 30, 2021, compared to \$981,845 at June 30, 2020.

Regeneus fell 0.1 cent or 1.3 percent to 7.6 cents.

LITTLE GREEN PHARMA

Little Green says revenue for the year to June 30, 2021 was up 217.8 percent to \$7,003,630 with last year's \$9,315,435 net loss after tax turned to a profit of \$24,603,555. Little Green said revenue was from sales of its medical marijuana products.

The company said that the profit from ordinary activities after tax "includes a gain on the bargain purchase of the Denmark facility of \$24,979,733".

In June, Little Green said it acquired Canopy Growth Denmark ApS, renamed Little Green Pharma Denmark ApS (BD: Jun 22, 2021).

The company said diluted loss per share turned to diluted earnings of 14.84 cents per share, with net tangible assets per share up 360.9 percent to 40.01 cents, and it had cash and equivalents of \$40,269,169 at June 30, 2021, compared to \$4,273,564 at June 30, 2020.

Little Green fell half a cent or 0.7 percent to 71.5 cents.

MEDLAB CLINICAL

Medlab says revenue for the year to June 30, 2021 was up 54.5 percent to \$4,399,412 with net loss after tax down 7.9 percent to \$12,418,478.

Medlab said revenue came primarily from sales of its probiotics and food additives. Medlab said diluted loss per share fell 29.6 percent to 4.18 cents, with net tangible assets per share up 4.8 percent to 4.36 cents, and it had cash and equivalents of \$13,434,762 at June 30, 2021, compared to \$9,063,044 at June 30, 2020.

Medlab fell half a cent or 2.8 percent to 17.5 cents.

BIOXYNE

Bioxyne says revenue for the year to June 30, 2021 was down 6.6 percent to \$2,110,377 with net loss after tax down 28.2 percent to \$425,725.

Bioxyne said revenue included \$1,815,462 from sales of its probiotic Lactobacillus fermentum VRI-003, along with interest and royalties.

The company said diluted loss per share was down 22.2 percent to 0.07 cents, with net tangible asset backing per share down 25 percent to 0.3 cents and it had cash and cash equivalents of \$1,602,210 at June 30, 2021, compared to \$1,747,886 at June 30, 2020. Bioxyne was unchanged at 3.3 cents.

INCANNEX HEALTHCARE

Incannex says revenue for the year to June 30, 2021 was up 210.7 percent to \$1,897,596 with net loss after tax up 73.8 percent to \$8,163,590.

Incannex said revenue came from the sale of its cannabinoid oil products.

The company said net tangible asset backing per share was up 90.5 percent to 0.80 cents, basic loss per share was up 38.3 percent to 0.83 cents and it had cash and cash equivalents of \$ 9,123,617 compared to \$3,603,390 at June 30, 2020.

Incannex was up half a cent or 1.2 percent to 42 cents with 7.5 million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says revenue for the year to June 30, 2021 was down 7.9 percent to \$1,310,824 with net loss after tax up 64.0 percent to \$2,859,663.

Proteomics said revenue came from analytical services to the biotechnology sector. The company said that basic loss per share was up 50.0 percent to 3.0 cents, net tangible asset backing per share was up 40.0 percent to 7.0 cents, and it had cash and cash equivalents of \$5,604,834 at June 30, 2021, compared to \$2,365,022 at June 30, 2020. Proteomics was unchanged at \$1.10.

OVENTUS MEDICAL

Oventus says revenue for the year to June 30, 2021 was up 159.8 percent to \$1,089,535 with net loss after tax down 2.9 percent to \$9,831,562.

Oventus said revenue was primarily from sales of its O2Vent sleep apnoea products. Oventus said diluted loss per share fell 21.7 percent to 6.07 cents with net tangible assets per share down 31.6 percent to 3.83 cents, and it had cash and equivalents of \$9,156,547

at June 30, 2021 compared to \$8,455,393 at June 30, 2020.

Oventus was unchanged at 10 cents.

ORTHOCELL

Orthocell says the last of 30 patients in its randomized trial of Ortho-ATI for rotator cuff tendinopathy and tear has completed their 12-month follow-up visit (BD: Jun 30, 2020). Orthocell said the trial was designed to assess the effectiveness of its autologous tenocyte implantation (Ortho-ATI) compared to corticosteroids, with final data collection and validation in progress, and results expected by the end of this year.

Orthocell managing-director Paul Anderson said the completed follow-up was "an important development milestone for Ortho-ATI and the company".

Orthocell fell half a cent or 1.1 percent to 46 cents.

PHARMAXIS

Pharmaxis says PXS-6302 is safe and well tolerated and achieved full inhibition of lysyl oxidase enzymes in skin with minimal systemic exposure.

Pharmaxis said that the phase I trial in in healthy volunteers at the University of Western Australia and Fiona Stanley Hospital was led by Prof Fiona Wood and tested PXS-6302 cream at four different strengths in four subjects as a single dose, scaling to the highest dose applied daily for seven days in a further six subjects.

The company said the positive results triggered a longer-term study in patients with scars, expected to begin by the end of the year.

Prof Wood said that two studies were planned with Pharmaxis, one in established scars and one in patients with burn injuries after they have had surgery.

Pharmaxis said the trial would investigate the safety of three months' treatment with PXS-6302, and explore whether three months' treatment could make a difference to both the appearance and structure of their scars.

Pharmaxis was up half a cent or 4.2 percent to 12.5 cents with 2.9 million shares traded.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says Emtinb "significantly reduced biomarkers for key drivers of dysfunctional immune responses in multiple sclerosis".

Neuroscientific said that the biomarkers related to inflammation, immunomodulation, and cell migration and the study was conducted in human primary cell-based systems by contract research organization Eurofins US.

The company said it previously reported "highly significant results" which showed that Emtinb increased survival of neurons, regenerated axons of neurons and upregulated the process of remyelination (BD: Mar 18, Jul 14, 2020).

Neuroscientific said that Emtinb increased myelin formation by more than 30 percent in comparison to leading multiple sclerosis drug Copaxone, in-vitro.

Neuroscientific managing-director Matt Liddelow said the results "further validate the disease modifying potential of Emtin as a treatment for multiple sclerosis".

"Unlike currently available drugs ... Emtinb has the potential to regulate immune processes, protect and regenerate nerve cells and upregulate myelination," he said. Neuroscientific rose one cent or three percent to 34 cents with 1.8 million shares traded.

IMMUTEP

Immutep says China's EOC Pharma is planning a trial of IMP321 in combination with an anti-programmed death-1 (PD-1) therapy, expected to begin by July 2022.

Immutep said that the trial of IMP321, also called eftilagimod alpha or efti and designated EOC202 in China, in combination with an anti- PD-1 therapy followed EOC's previously announced phase II trial evaluating IMP321 in combination with chemotherapy in metastatic breast cancer patients, which was expected to begin this year.

Immutep chief executive officer Marc Voigt said that EOC was "expanding its clinical trial pipeline, adding a new combination therapy study of efti with an anti-PD-1 drug".

"This is the same promising concept we are evaluating in Tacti-002 and Tacti-003, for example," Mr Voigt said.

Immutep said that IMP321 was licenced to EOC for Greater China and EOC had responsibility for the development and commercialization in the territory, with Immutep eligible for development-based milestone payments and sales-based royalties. Immutep was up one cent or 1.9 percent to 53 cents with 2.3 million shares traded.

PHARMAUST

Pharmaust says that wholly-owned synthetic and medicinal chemistry subsidiary Epichem has paid a \$466,000 loan for a Perth laboratory expansion.

Pharmaust said that in 2015 Epichem received a \$750,000 loan from Federal Governments Export Finance Australia for a laboratory and that was repaid in July 2019. The company said that Epichem built a second laboratory at the site and borrowed \$466,000 from Export Finance Australia.

Pharmaust said Epichem had repaid two loans for "state of the art laboratories at Technology Park ... [and] the money saved on interest and principal will go straight to improving the bottom line".

Epichem chief executive officer Colin La Galia said the subsidiary's "ability to repay the loan without deferral over six years demonstrates the strength of this specialist business". Pharmaust was up 0.1 cents or 1.2 percent to 8.5 cents.

CYNATA THERAPEUTICS

Cynata says that the Canadian Intellectual Property Office has allowed a patent covering its Cymerus mesenchymal stem cell technology.

Cynata said that the patent, titled 'Methods and materials for haemato-endothelial differentiation of human pluripotent stem cells under defined conditions' would provide intellectual property protection until March 12, 2034.

The company said that the patent was owned by the University of Wisconsin-Madison's Wisconsin Alumni Research Foundation, it had an exclusive licence to the intellectual property and the inventors named on the patent were Cynata founder Prof Igor Slukvin and Dr Gene Uenishi.

Cynata chief executive officer Dr Ross Macdonald said the patent "adds an additional layer to our already comprehensive patent portfolio".

"The Cymerus platform enables manufacture of consistent, high-quality mesenchymal stem cells at scale," Dr Macdonald said. "This unique and valuable characteristic of Cynata's technology is key to the development of off-the-shelf therapeutic stem cell products to target a range of devastating diseases worldwide."

Cynata was up half a cent or one percent to 52 cents.

CRESO PHARMA

Creso says it has terminated its proposed merger with Red Light Holland Corp but would pursue a Nasdag listing.

In June, Creso announced the proposed merger with Red Light Holland and said it has completed a dual listing on the US Over The Counter Quality Exchange second board (OTCQB) under the code 'COPHF' (BD: Jun 11, 17, 2021).

Today, the company said that "favorable US regulatory changes will occur soon and that retaining an ASX listing and pursuing a dual Nasdaq listing will provide the best vehicle to pursue North American-focused growth opportunities".

The company said it would continue to work with Red Light Holland which had ordered \$170,000 of its marijuana products "demonstrating commitment".

Creso said that California was in advanced stages of legalizing the possession of psychedelics including psilocybin and Lysergic acid diethylamide (LSD).

The company said it had mandated New York corporate advisory firm, EAS Advisors LLC for the Nasdag listing.

Creso was up one cent or 8.3 percent to 13 cents with 28.0 million shares traded.

AROA BIOSURGERY

Movac Fund 3 says it has ceased its substantial shareholding in Aroa, distributing 18,679,050 shares in an in-specie distribution to partners.

The Wellington, New Zealand-based Movac said the distribution took place on August 30, 2021.

Aroa fell four cents or 3.7 percent to \$1.05.

EXOPHARM

Exopharm says it has appointed advisor Dr Jennifer King as an independent non-executive director, effective from September 1, 2021.

Exopharm said that Dr King was previously an executive with Shire Human Genetic Therapies and Shire Pharmaceuticals and more recently was Intellia Therapeutics Inchead of business development.

The company said that Dr King held a Bachelor of Science from Massachusetts Institute of Technology, a Doctor of Philosophy from Stanford University School of Medicine and a Master of Business Administration from Boston's Northeastern University.

Exopharm was up four cents or 8.5 percent to 51 cents.