Biotech Daily

Thursday August 12, 2021

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: PROTEOMICS UP 11%; ANTISENSE DOWN 10%**

*** PHARMAXIS REVENUE UP 207% TO $22.7m, LOSS DOWN 79% TO $3m**

*** ANTISENSE: FDA WANTS MORE DATA FOR ATL1102 DMD APPLICATION**

*** PROTEOMICS HIRES BIOTEM FOR PROMARKERD KIDNEY DISEASE KITS**

*** IMAGION, GCT WORK ON NANO-SCINTILLATOR FOR BREAST CANCER**

*** AUSTRALIA ALLOWS EYE CO PATENT FOR GEOGRAPHIC ATROPHY**

*** VGI: INFORMED SPORT CERTIFIES NE1-ELITE 'NO BANNED SUBSTANCES'**

*** DIMERIX REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** CRESO REQUESTS 'CANADA HEALTH LICENCE' TRADING HALT**

*** FACTOR TO HOLD 10-TO-1 CONSOLIDATION**

*** JASON CARROLL TAKES 5% OF ISLAND**

*** OSPREY APPOINTS MARTIN EMERSON DIRECTOR**

MARKET REPORT

The Australian stock market edged up 0.05 percent on Thursday August 12, 2021, with the ASX200 up 3.9 points to 7,588.2 points. Eleven of the Biotech Daily Top 40 stocks were up, 19 fell, seven traded unchanged and three were untraded. All three Big Caps fell.

Proteomics was the best, up 11.5 cents or 11.0 percent to $1.16, with 113,425 shares traded. Neuren climbed 9.3 percent; LBT was up 6.1 percent; Actinogen and Imugene improved more than five percent; Cyclopharm, Mesoblast, Nova Eye and Prescient rose more than two percent; with Next Science and Opthea up by more than one percent.

Antisense led the falls, down two cents or 10 percent to 18 cents, with 7.7 million shares traded. Osprey lost 7.1 percent; Universal Biosensors fell 4.4 percent; Avita, Cynata, Medical Developments and Telix were down more than three percent; Alterity and Amplia shed more than two percent; Cochlear, Genetic Signatures, Immutep, Nanosonics, Oncosil, Polynovo and Pro Medicus were down one percent or more; with Clinuvel, CSL, Orthocell, Paradigm, Resmed and Volpara down by less than one percent.

PHARMAXIS

Pharmaxis says revenue for the year to June 30, 2021 was up 207.1 percent to $22,679,000 with loss down 78.7 percent to $2,970,000.
Pharmaxis said that the revenue included $14,017,000 in milestone payments and Biotech Daily has excluded various grants including the Federal Government Research and Development Tax Incentive.
The company said its income from the sale of goods, bank interest and the sale of distribution rights was up 17.4 percent from $7,391,000 to $8,680,000.
Pharmaxis said that revenue from sales of its lung function test Aridol for asthma and its inhaled dry powder Bronchitol for cystic fibrosis fell 4.9 percent to $6,680,000 compared to the previous corresponding period.
Pharmaxis said that Bronchitol sales slipped 0.5 percent to $5,235,000, while sales of Aridol fell 18.1 percent to $1,445,000.
The company said that net tangible assets per share were constant at zero cents, with diluted loss per share 0.7 cents compared to last year's 3.5 cents.
Pharmaxis said it had cash and cash equivalents of $18,712,000 at June 30, 2021 compared to $14,764,000 at June 30, 2020.
Pharmaxis was unchanged at 9.5 cents.

ANTISENSE THERAPEUTICS

Antisense says that the US Food and Drug Administration requires updated clinical and toxicology protocols to be resubmitted to lift the ATL1102 partial clinical hold.
In 2017, Antisense said the FDA had lifted the clinical hold on its phase IIb trial of ATL1102 for multiple sclerosis, approving the trial at a 25mg/week dose for six months (BD: Oct 2, 2017).
In 2008, Antisense and then partner Teva reported safety and efficacy of ATL1102 in a phase IIa trial for multiple sclerosis at 400mg per week, with the only concern a reduction in blood platelets, or thrombocytopenia, which was reversed after treatment interruption (BD: Jun 30, 2008).
Today, Antisense said that the partial clinical hold limited dosing of ATL1102 to 25mg per week for six months and further documentation to lift that hold was required.
The company said that prior to fast-track designation being granted, "the regulatory process for lifting the ATL1102 investigational new drug partial clinical hold … must be completed".
Antisense said it was working with its advisors on the revised study protocols.
The company quoted the FDA saying that Duchenne muscular dystrophy was "a serious condition, and it appears that ATL1102 may have the potential to demonstrate an effect on a serious aspect of the condition and provide benefit over currently approved therapies".
"We cannot determine whether the overall development plan will enable you to obtain the data necessary to evaluate whether your product meets this unmet medical need because your [investigational new drug application] is currently on partial hold," the FDA was reported saying.
"We recommend that you send a new request for fast-track designation after the partial hold issues are resolved," Antisense quoted the FDA.
The company said the FDA feedback was "positive" and it intended to resubmit its clinical trial protocol to have the current partial clinical hold on ATL1102 lifted.
Antisense said it also expected to submit "the protocol synopsis for a nine-month chronic monkey toxicology study to support the dosing of patients beyond six months".
Antisense fell two cents or 10 percent to 18 cents with 7.7 million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has contracted French immuno-assay specialist Biotem to manufacture its Promarkerd test kits for diabetic kidney disease.
Proteomics says the test kits will be combined with reagents being produced by Abcam to identify a unique protein 'fingerprint' in the blood indicating diabetic kidney disease.
The company said that the Apprieu, France-based Biotem was an ISO13485-certified company, which produced specialized immuno-technology products, including enzyme-linked immunosorbent assays (Elisa) and lateral flow immuno-assays.
Proteomics managing-director Dr Richard Lipscombe said that hiring Biotem and Abcam were "key elements in achieving the company's goal of selling a test with full regulatory approvals at scale worldwide".
"Currently, the Promarkerd immunoassay Elisa kits are manufactured under licence in Australia," Dr Lipscombe said. "By contracting these specialist manufacturers, we are building our production capacity to meet our anticipated demand for the test in the Northern Hemisphere and worldwide."
Proteomics was up 11.5 cents or 11.0 percent to $1.16.

IMAGION BIOSYSTEMS

Imagion Biosystems says it has a joint development agreement with Global Cancer Technology (GCT) to develop nano-scintillator technology for breast cancer.
Imagion says that the San Diego, California-based Global Cancer Technology licenced the nano-scintillator technology from the University of California San Diego.
The company said the technology was also known as scintillating nanocrystals, which emit photons when activated by low dose gamma radiation, and enabled a controlled release of a therapeutic agent, with the approach, known as x-ray-induced photodynamic therapy, had the potential to deliver a more localized and effective dose of drug to treat cancers.
The company said it had been working with Global Cancer Technology over the past year and that the joint work on its nano-scintillators would support the company as it developed its Magsense cancer imaging technology.
Imagion said it would be paid for certain research and development services and gain an ownership interest in the arising nano-scintillator product.
Imagion executive chair Bob Proulx said that the project was "value adding to our mission of developing nano-particle-based imaging agents and therapies".
"As we continue to develop the Magsense imaging technology, the nano-scintillators provide Imagion with a foothold to a unique high-value therapeutic product," he said.
Imagion was up 0.3 cents or 3.85 percent to 8.1 cents with 14.6 million shares traded.

EYE CO PTY LTD

Eye Co says that the Australia Patent Office (IP Australia) has allowed a key patent relating to its fludrocortisone acetate for geographic atrophy.
Eye Co said the patent, titled 'Composition and method of treatment for dry AMD' would protect its intellectual property until 2039.
The company said that geographic atrophy was a macular atrophy associated with dry age-related macular degeneration (AMD) and the patent also covered combinational use with anti-vascular endothelial growth factor (VEGF) technology.
Eye Co said it was "close to concluding a phase Ib safety study" involving fludrocortisone acetate for dry AMD for which there were no available treatments.
Eye Co is a private company.

VGI HEALTH TECHNOLOGY (FORMERLY AZURE HEALTHCARE, INVICTUS)

VGI says that the Lexington, Kentucky-based Informed Sport has certified its NE1-Elite sports food additive for muscle soreness, as not containing banned substances.
VGI said that Informed Sport certified products provided the sports supplement industry with “the highest standard of quality assurance”.
The company said that Informed Sport testing was “significantly more sensitive than [good manufacturing practice] regulation testing” with every batch tested for more than 200 banned substances.
VGI said that the Informed Sport logo was “the mark of quality targeted at athletes of all levels”.
The company said the certification meant that athletes and members of the armed forces who were required to take banned substance testing could use the products “with complete confidence”.
VGI said that Informed Sport Certification was recognized world-wide.
VGI subsidiary Invictus Nutraceuticals chief executive officer Richard Estalella said that the Informed Sport certification “opens up the professional sports and armed forces markets which we previously would have had difficulty in penetrating”.
“This certification provides sportspeople and members of the armed forces with the confidence that every batch of NE1-Elite, which has been clinically proven to reduce delayed onset muscle soreness and improve muscle recovery after exercise, has been tested for a wide range of substances prohibited in sport,” Mr Estalella said.
On the National Stock Exchange, VGI closed untraded at 15 cents.

DIMERIX

Dimerix has requested a trading halt “for the purposes of considering, planning and executing a capital raising”.
Trading will resume on August 16, 2021, or on an earlier announcement.
Dimerix last traded at 23.5 cents.

CRESO PHARMA

Creso says it has requested a trading halt “pending an announcement regarding the receipt of a material licence from Health Canada”.
Trading will resume on August 16, 2021, or on an earlier announcement.
Creso last traded at 13 cents.

FACTOR THERAPEUTICS

Factor Therapeutics says it will hold a 10-to-one consolidation of its shares and options.
On Tuesday, Factor said it would hold an extraordinary general meeting to approve the acquisition of Powerlime Inc and rename itself Dominion Minerals (BD: Aug 10, 2021).
Today, the company said the record date for the consolidation would be September 14, with trading of the consolidated shares to begin on September 22, 2021.
Factor said it currently had 1,042,835,633 shares on offer, which would be consolidated to 104,283,563 shares.
The company said its 2,250,000 unquoted options would become 225,000 unquoted options, following the consolidation.
Factor was in a suspension and last traded at 0.5 cents.

ISLAND PHARMACEUTICALS

Jason Allan Carrol says he has become a substantial share-holder in Island Pharmaceuticals with 4,050,000 shares or 5.0 percent.

The Melbourne-based Mr Carroll said that the shares were acquired between July 2 and August 10, 2021, with the largest acquisition 550,000 shares for $185,949 or 33.8 cents a share.

Island was up one cent or 2.8 percent to 37 cents.

OSPREY MEDICAL

Osprey says it has appointed Martin Emerson as a director, effective from today.

Osprey said Mr Emerson had more than 35 years' experience in healthcare in market development and expansion.

The company said that previously Mr Emerson was American Medical System and Galil Medical's chief executive officer and was currently the Minneapolis, Minnesota-based Monteris Medical's chief executive officer.

Osprey fell 0.1 cents or 7.1 percent to 1.3 cents.