Biotech Daily

Thursday December 9, 2021

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: NEUREN UP 22%; COMPUMEDICS DOWN 4%**

*** MTP $19.7m MEDICAL DEVICE INITIATIVE**

*** SERVATUS 'OVERSUBSCRIBED' PLACEMENT RAISES $7.5m**

*** EPSILON RAISES $2.9m**

*** 4D MEDICAL: I-MED 1st XV LVAS COMMERCIAL SCAN**

*** PACIFIC EDGE: NORTHERN HEALTH TO USE CXBLADDER CANCER TEST**

*** MEMPHASYS, MONASH IVF BEGIN FELIX SPERM SEPARATION TRIAL**

*** ADALTA: NEBULIZED AD-214 REACHES ALVEOLAR, IN MICE**

*** ANTISENSE SUBMITS FDA ATL1102 TOXICOLOGY PROTOCOL**

*** PALLA PLEADS 'SHAREHOLDER' TO 41.2% FALL**

*** ARGENICA: USPTO ALLOWS ARG-007 PATENT**

*** AUSCANN: FDA CONFIRMS DOG OA MARIJUANA CPAT-01 TRIAL**

*** MACQUARIE GROUP BELOW 5% IN PATRYS**

*** COPIA BELOW 5% IN PROBIOTEC**

*** ATOMO LOSES DIRECTOR CONNIE CARNABUCI**

*** AUDEARA APPOINTS DR ELAINE SAUNDERS DIRECTOR**

*** NATHAN JONG REPLACES IMUGENE CO-CO SEC JUSTYN STEDWELL**

*** ACTINOGEN APPOINTS 2 XANAMEM ADVISORY BOARDS**

MARKET REPORT

The Australian stock market fell 0.28 percent on Thursday December 9, 2021, with the ASX200 down 20.9 points to 7,384.5 points. Twenty-two of the Biotech Daily Top 40 stocks were up, 10 fell and eight traded unchanged.

Neuren was the best, up 70 cents or 21.9 percent to $3.90, with 3.9 million shares traded. Opthea climbed 7.3 percent; Imugene improved 6.25 percent; Immutep, Nova Eye and Osprey were up more than five percent; Actinogen, Starpharma, Telix and Universal Biosensors climbed more than four percent; LBT was up 3.3 percent; Antisense, Nanosonics, Paradigm, Pharmaxis and Prescient rose more than two percent; Cynata, Oncosil and Volpara were up more than one percent; with CSL, Orthocell, Pro Medicus, Proteomics and Resmed up less than one percent.

Compumedics led the falls, down 1.5 cents or 3.8 percent to 38 cents, with 25,809 shares traded. Amplia, Clinuvel, Impedimed, Kazia and Next Science fell more than two percent; Avita, Cyclopharm, Mesoblast and Polynovo were down more than two percent; with Cochlear down 0.5 percent.

MTP CONNECT

MTP Connect says it has launched $19.75 million funding initiative “to identify and nurture high-quality medical device projects with strong commercial potential.”
MTP Connect said The Clinical Translation and Commercialisation – Medtech program was funded by the Federal Government’s Medical Research Future Fund.
MTP Connect managing-director Dr Dan Grant said the program would offer financial assistance, educational support and infrastructure access to Australian small to medium-sized enterprises.
“By identifying new medical devices that have the potential to improve the health and well-being of Australians, and subsequently supporting their translation, the program will help de-risk projects, making them attractive to private investment for the final steps towards commercialization,” Dr Grant said.
Dr Grant said MTP had selected five industry partners as part of the program: the Medical Technology Association of Australia, the Medical Device Partnering Program, Cicada Innovations, the Bridgetech Program and Therapeutic Innovation Australia.
Dr Grant said that the program would deliver consultation and commercialization support, education and access to engineering, fabrication and prototyping facilities “critical for moving projects through the clinical stage of product development”.
Dr Grants said that in addition to funding the program was designed “to leverage the expertise of our partners to help [small to medium sized enterprises] turn their early clinical innovations into medical devices that can improve the health of Australians, while also generating commercial returns and helping create high-paying jobs”.
Dr Grant said that the first funding round would open on December 17, 2021 and would award funding of $250,000 to $1.5 million to eligible projects over 24 months.
For more information go to: https://www.mtpconnect.org.au/programs/ctcm.

SERVATUS

Servatus says it has raised $7.5 million in an ‘oversubscribed’ capital raise to sophisticated shareholders for its “live microbial and engineered protein bio-therapeutics”.
The Coolum, Queensland-based Servatus said the majority of funds would go to clinical trials for insomnia, rheumatoid arthritis and inflammatory bowel disease-ulcerative colitis, which it hoped to begin in Queensland and the US “in early 2022”.
Servatus is a public unlisted company.

EPSILON HEALTHCARE

Epsilon says it has raised $2.9 million in a placement at nine cents a share, a 14.6 percent discount to the 10-day volume weighted average price to December 6, 2021.
Epsilon said that subject to shareholder approval, the professionals and sophisticated investors led by CPS Capital would receive one option for every two shares subscribed, exercisable at 15 cents each within three years.
Epsilon said the funds would be used to expand production at the Gold Coast Queensland Southport facility, expanding its Tetra Health clinics network and provide additional working capital.
Epsilon said CPS Capital was the lead manager for the capital raising and subject to shareholder approval would receive about 16.11 million placement options.
Epsilon fell 0.9 cents or nine percent to 9.1 cents with 4.4 million shares traded.

4D MEDICAL

4D Medical says the I-Med Radiology Network has completed the first commercial respiratory scans using its XV lung ventilation analysis software.
4D said it had a strategy to make “state-of-the-art respiratory scans” and reports available to general practitioners and specialists on a pay-per-scan basis.
4D chief executive officer Dr Andreas Fouras said clinicians at the Casey region could refer patients for “four-dimensional respiratory scanning”.
“The ability for these [general practitioners] and respiratory specialists to interpret ventilation reports that inform interventions and treatment is a world’s first achievement in improving patient care,” Dr Fouras said.
4D Medical fell half a cent or 0.4 percent to $1.18.

PACIFIC EDGE

Pacific Edge says an agreement with Melbourne’s Northern Health to use its Cxbladder cancer monitor is its “first commercial agreement of scale in Australia”.
Pacific Edge said that Northern Health provided healthcare to the Northern Hospital Epping, Broadmeadows Hospital, Bundoora Centre and Craigieburn Centre.
The company said the Cxbladder monitor would be used “to identify those patients who can safely forego or defer a flexible cystoscopy at their next scheduled hospital visit”.
“Once implemented, the service will be extended to use Cxbladder Triage for the evaluation of patients referred to urology for investigation of haematuria [or] blood in the urine and a key indicator of bladder cancer,” Pacific Edge said.
The company said Northern Health would coordinate patient sample collection, and shipping to Pacific Edge for analysis at its laboratory in Dunedin, New Zealand.
Pacific Edge chief executive officer David Darling said the agreement was “another in-market validation of Cxbladder’s clinical utility in a large healthcare network”.
Pacific Edge was up 3.5 cents or 2.9 percent to $1.26.

MEMPHASYS

Memphasys says with Monash IVF (in-vitro fertilization) group, it will conduct a 104-couple trial of its Felix sperm separation device at four sites in New South Wales and Victoria.
Memphasys said Mobius Medical was its contract research organization and the study’s aim was to “statistically prove the Felix system is not inferior to either of the current commercial sperm separation techniques” discontinuous gradient centrifuge (DGC) and “swim-up”, which were used to prepare sperm for intra-cytoplasmic sperm injection, a common in-vitro fertilization procedure.
Memphasys said the trial would be a ‘sibling split’ and blinded study, with half of the harvested eggs fertilized with sperm processed by the Felix system and the other half fertilized by sperm processed by either the DGC or the swim-up technique, and was expected to begin in March 2022 to be completed by the end of 2022.
Memphasys chair Alison Coutts said the study was “an important milestone on the path to securing regulatory approval in Australia and … in key markets such as the US”.
“We have already sold a Felix system to a Chinese [key opinion leader] site for research purposes and this trial should accelerate interest in further research sales in the future,” Ms Coutts said. “It will also supplement the current commercialization of the Felix system in markets with lower regulatory hurdles where sales can occur now, such as Japan, India, Canada and New Zealand.”
Memphasys was up half a cent or 5.5 percent to 9.6 cents.

ADALTA

Adalta says results from two studies of its inhaled version of AD-214 in nebulization devices for fibrosis reached the smallest airways in mice and “exceeded expectations”.
In October, Adalta said it would reallocate $760,000 to develop an inhaled version AD-214 for fibrosis (BD: Oct 7, 2021).
Today, the company said it was developing a “patient-preferred and lower cost inhaled formulation of AD-214 for future clinical studies in idiopathic pulmonary fibrosis (IPF)”.
Adalta said in the first study, AD-214 was passed through a micro-spray used to administer bleomycin, an anti-cancer chemotherapy drug, to the lungs of mice.
Adalta said AD-214 was shown to bind to its target, CXCR4, after passing through the micro-spray without signs of aggregation or degradation.
The company said efficacy studies of AD-214 delivered by micro-spray in a bleomycin mouse model of idiopathic pulmonary fibrosis had begun at Shanghai’s Pharmalegacy Laboratories Co Ltd, with initial results expected “early in 2022”.
Adalta said in the second study, AD-214 was nebulized in “two commercially available nebulizers suitable for human use”.
Adalta said the objective was to ensure nebulizers produced greater than 50 percent fine particle fraction and greater than 10 percent deposition in alveolar, or the small airways, of the lungs which was important for idiopathic pulmonary fibrosis (IPF) therapy.
The company said the study conducted at the Chippenham, England-based Vectura Ltd showed that up to 69 percent of the delivered dose was deposited in the lungs.
Adalta chief executive officer Dr Tim Oldham said that “the results of these studies support AD-214 being delivered by inhalation without losing its ability to bind to CXCR4 and at particle sizes with potential to travel to the furthest reaches of the lungs that are most affected by IPF”.
“Simulations of the dose deposited in these regions exceeded our initial expectations,” Dr Oldham said.
“These results give us even greater confidence that we can deliver an inhaled formulation in time for scheduled future clinical studies,” Dr Oldham said.
Adalta was up 0.7 cents or 9.5 percent to 8.1 cents.

ANTISENSE THERAPEUTICS

Antisense says it has filed a toxicology report to the US Food and Drug Administration to support and extend the use of ATL1102 for Duchenne muscular dystrophy.
Antisense said it was expecting FDA feedback on the toxicology protocol synopsis by April 2022 on a planned nine-month chronic monkey toxicology study to support the dosing of patients with ATL1102 beyond six months in US.
In August, the company said that the US Food and Drug Administration required updated clinical and toxicology protocols to be resubmitted to lift the ATL1102 partial clinical hold (BD: Aug 12, 2021).
Today, Antisense said a type C guidance meeting with the FDA earlier in the year provided it with clarity on the requirement for the monkey study and design of a phase IIb or phase III trial for the US.
Antisense said FDA interactions would continue in parallel with the phase IIb/III pivotal trial in Europe.
The company said based on the trial’s success, it could receive a rare paediatric disease priority review voucher if ATL1102 received FDA approval for Duchenne muscular dystrophy before September 30, 2026.
Antisense was up half a cent or 2.8 percent to 18.5 cents with 2.1 million shares traded.

PALLA PHARMA

Palla Pharma has told the ASX that it is not aware of any information it has not announced which, if known, could explain the recent trading in its securities.
The ASX said the company's share price fell 14 cents or 41.2 cents from a high of 34 cents yesterday, on December 8, to a low of 20 cents, today, December 9, 2021.
Palla said that "some, but not all of the recent trading in its securities may be as a result of a shareholder seeking to realize its investment following a change in portfolio manager".
The company said that "given the generally small number of shares traded, any sale by a shareholder of a sizeable parcel of shares could have a material impact on the price".
According to Commsec data, 20 cents is Palla's lowest share price since 2016.
Palla closed down five cents or 14.5 percent at 29.5 cents with 1.9 million shares traded.

ARGENICA THERAPEUTICS

Argenica says that the US Patent and Trademark Office has allowed a patent relating to neuroprotective peptides and lead drug candidate ARG-007.
Argenica said the patent, titled 'Neuroprotective Peptides' related to the use of ARG-007 as a therapeutic for stroke, traumatic brain injury and hypoxic-ischemic encephalopathy.
The company said the claims covered the use of ARG-007 for Alzheimer's disease, Huntington's disease, multiple sclerosis, Parkinson's disease, motor neuron disease, neuropathic pain, spinal cord injury, and epilepsy
Argenica said it expected the patent would provide coverage until at least 2034, with a patent term adjustment requested which would provide an additional one to two years.
Argenica was up 7.75 cents or 11.6 percent to 74.5 cents.

AUSCANN GROUP (MERGED WITH CANNPAL)

Auscann says the US Food and Drug Administration has confirmed that its marijuana-based CPAT-01 program for dogs with osteoarthritis is "consistent with its expectations".
In October, Auscann said it requested a meeting with the US Food and Drug Administration's Centre for Veterinary Medicine for CPAT-01 for pain relief in dogs with osteoarthritis (BD: Oct 18, 2021).
Today, the company said the Centre for Veterinary Centre "confirmed that the development program and strategy for CPAT-01 IS consistent with its expectations and were highly engaged in the meeting".
Auscann said a memorandum of conference with formal guidance from the meeting would be provided within 45 days, and based on the feedback from the agency, the company "is confident that there is a predictable pathway to approval for CPAT-01".
Auscann chief executive officer Layton Mills said the company was "delighted with the positive feedback, engagement and encouragement from the FDA-CVM at our [pre-submission] meeting and are rapidly moving forward with our … program to support the registration of CPAT-01 in the US".
Auscann was unchanged at 8.4 cents.

PATRYS

Sydney's Macquarie Group says it has ceased its substantial shareholding in Patrys.
Macquarie Group said that in more than 600 trades, it bought, sold and transferred shares between November 9 and December 6, 2021, at 3.5 and 4.0 cents a share.
Patrys was unchanged at 3.7 cents with 4.9 million shares traded.

PROBIOTEC

Copia Investment Partners say it has ceased its substantial shareholding in Probiotec.
The Melbourne-based Copia said that between November 8 and December 7, 2021, it bought and sold shares at prices ranging from $2.02 and $2.20 a share.
Biotech Daily calculates that Copia retains 3,975,000 shares Probiotec or 4.89 percent.
Probiotec was up seven cents or 3.3 percent to $2.22.

ATOMO DIAGNOSTICS

Atomo says that two-year director Connie Carnabuci has resigned as a non-executive director from today.
Atomo said Ms Carnabuci was appointed as a director on February 4, 2020.
Atomo fell half a cent or 2.8 percent to 17.5 cents with 6.9 million shares traded.

AUDEARA

Audeara says it has appointed Dr Elaine Saunders as non-executive director, effective from January 1, 2022.
Audeara said Dr Saunders started her career in the British National Health Service and co-founded Blamey Saunders Hears and Dynamic Hearing Pty Ltd.
Audeara was unchanged at 12 cents.

IMUGENE

Imugene says Nathan Jong replaced co-company secretary Justyn Stedwell effective from December 8, 2021.
Imugene said Mr Jong was a chartered accountant with more than 10 years of experience.
Imugene was up three cents or 6.25 percent to 51 cents with 28.1 million shares traded.

ACTINOGEN MEDICAL

Actinogen says it has appointed Prof Elizabeth Berry-Kravis, Prof Pam Ventola, Prof John Harrison and Dr Dana Hilt to its Fragile X and depression and cognition advisory boards.
Actinogen said Prof Berry-Kravis and Prof Ventola were appointed to the Fragile X syndrome clinical advisory board, while Prof Harrison and Dr Hilt were appointed to the depression and cognition clinical advisory board.
The company said Prof Berry-Kravis was a professor of pediatrics, neurological sciences, and biochemistry at Rush University Medical Centre in Chicago.
Actinogen said Prof Ventola was a professor at the New Haven, Connecticut-based Yale Child Study Centre and had more than 20 years' experience in developmental disabilities.
Actinogen said Prof Harrison was the principal consultant at the Bath England-based Metis Cognition and a visiting professor at King's College London.
The company said Dr Hilt was the chief medical officer at the Lexington, Massachusetts-based Frequency Therapeutics.
Actinogen was up half a cent or 4.2 percent to 12.5 cents with 3.5 million shares traded.