Biotech Daily

Tuesday December 7, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: NEUREN UP 91%; OSPREY DOWN 5%**

*** NEUREN PHASE III TROFINETIDE RETT TRIAL SUCCESS; UP 109%**

*** ALCIDION HOPES TO RAISE $55m FOR SILVERLINK; TRADING HALT**

*** ACTINOGEN, OXFORD UNI XANAMEM CORTISOL COLLABORATION**

*** VICTORIA BACKS COMPUMEDICS SOMFIT MANUFACTURE**

*** RECCE: 'R327 CLEARS BURN INFECTIONS IN 5 DAYS'**

*** IMUGENE: 1st CHECKVACC PATIENT CLEARS SAFETY**

*** ANTERIS: EVOLUTION UNDERWRITES $14.6m OPTION EXERCISE**

*** STARPHARMA, GENENTECH DEP RESEARCH AGREEMENT**

*** VGI APPLIES FOR PCT DRUG DELIVERY PATENT**

*** ORTHOCELL REQUESTS 'ORTHO-ATI STUDY RESULTS' TRADING HALT**

*** EPSILON REQUESTS 'CPS CAPITAL RAISING' TRADING HALT**

*** CLARITY RELEASES 6.6m ASX ESCROW SHARES**

MARKET REPORT

The Australian stock market was up 0.95 percent on Tuesday December 7, 2021, with the ASX200 up 68.8 points to 7,313.9 points. Twenty-two of the Biotech Daily Top 40 stocks were up, seven fell, 10 traded unchanged and one was untraded. All three Big Caps rose.

Neuren was the best, up $1.55 or 91.2 percent to $3.25, with 10.1 million shares traded (see below). Telix climbed 9.9 percent; Actinogen improved 8.7 percent; Polynovo was up 7.7 percent; Amplia, Immutep, Opthea and Optiscan were up more than five percent; Starpharma and Uscom climbed more than four percent; Cynata, Impedimed, Nanosonics, Paradigm and Universal Biosensors were up more than three percent; Avita and Prescient rose more than two percent; Clinuvel, Cochlear, CSL, Imugene and Medical Developments were up more than one percent; with Pro Medicus, Proteomics and Resmed up by less than one percent.

Osprey led the falls, down 3.5 cents or 4.9 percent to 68 cents, with 43,108 shares traded. Dimerix, Next Science and Oncosil shed more than two percent; with Kazia, Mesoblast and Nova Eye down by less than one percent.

NEUREN PHARMACEUTICALS

Neuren says that a 187-patient, phase III trial of trofinetide shows statistically significant benefit for Rett syndrome compared to placebo, for both co-primary endpoints.

Neuren said that its North America partner, the San Diego, California-based Acadia Pharmaceuticals, reported “statistically significant improvement over placebo in the Rett syndrome behavior questionnaire (p = 0.0175) and the clinical global impression of improvement (p = 0.0030).

In 2019, Neuren said Acadia had begun the phase III, 12-week, double-blind, randomized, placebo-controlled, ‘Lavender’ trial, and previously said that Acadia would pay $630 million in upfront fees, milestones and royalties for North American rights to trofinetide (BD: Aug 7, 2018, Feb 4, Oct 31, 2019).

Neuren said that development and trial costs would be funded by Acadia and Neuren would have free and full access to all data to commercialize outside North America.

In 2020, Neuren said the US Food and Drug Administration had awarded Acadia rare paediatric disease designation for the US study of trofinetide for Rett syndrome, with Acadia eligible for a priority review voucher, with Neuren to receive one third of the market value of the voucher (BD: Mar 4, 2020).

The company said that in 2019, two vouchers were sold for $US105 million ($A159.2 million) and $US95 million ($A144.0 million).

Today, Neuren said it was eligible to receive potential milestone payments of up to $US455 million plus tiered escalating double-digit percentage royalties on net sales of trofinetide in North America, and it would earn revenue over 2022 and 2023 for Rett syndrome in the US alone of $111 million plus double-digit percentage royalties on net sales if a new drug application was approved by the FDA and trofinetide was launched in the US, and it expected to engage commercial partners for Europe and Asia.

Today, the company said that trofinetide met the trial’s co-primary efficacy endpoints of statistically significant improvement over placebo in the Rett syndrome behavior questionnaire and the clinical global impression of improvement, as well as key secondary endpoints, including the caregiver scale of ability to communicate.

Neuren said that Acadia planned to conduct a pre-new drug application meeting with the FDA by April 2022 for a new drug application “around mid-year 2022”.

An attached media release from Acadia said that discontinuation rates related to treatment emergent adverse events, with 17.2 percent in the trofinetide group compared to 2.1 percent in the placebo group.

Acadia said that the most common adverse events were diarrhoea in which the trofinetide group had an 80.6 percent rate compared to 19.1 percent with placebo, of which 97.3 percent in the trofinetide arm “were characterized as mild-to-moderate” and vomiting which had 26.9 percent with trofinetide compared to 9.6 percent with placebo, “of which 96 percent in the trofinetide arm were characterized as mild-to-moderate”.

Acadia said that serious adverse events were observed in 3.2 percent of study participants in both the trofinetide and placebo groups.

Acadia said that patients completing the Lavender study had the opportunity to continue to receive trofinetide in the open-label Lilac and Lilac-2 extension studies, with more than 95 percent of participants who completed the Lavender study electing to roll-over to the Lilac open-label extension study.

Neuren chief executive officer Jon Pilcher said the company was “delighted with these robustly positive results and are now eager to see trofinetide progress through the regulatory approval process”.

Neuren climbed as much as 109.4 percent to $3.56, before closing up $1.55 or 91.2 percent at $3.25 with 10.1 million shares traded.

ALCIDION

Alcidion says it hopes to raise $55 million at 25 cents a share to acquire the Newcastle, England-based Silverlink Software for its patient administration systems.
Alcidion said it had “firm commitments” to raise $30 million in a placement and hoped to raise a further $25 million through an underwritten institutional and retail one-for-10.5 underwritten rights offer.
The company said that the 25-cent price was a 21.9 percent discount to its last closing price on December 6, 2021.
Alcidion said the capital raise would pay for the GBP30.0 million ($A56.3 million) purchase price for Silverlink, with a further GBP3.0 million ($A5.6 million) subject to the earn-out, based on the successful renewal of selected customers by March 31, 2024.
The company said the record date for rights offer would be December 9, it would open on December 14 and close on December 23, 2021.
Alcidion said Henslow Pty Ltd and Canaccord Genuity (Australia) were the joint lead managers and joint bookrunners.
The company said that patient administration systems (PAS) were “the foundation of hospital [information technology] systems” capturing all non-clinical information used in the hospital management including registrations, admissions, bed occupancy and discharge.
Alcidion said that Silverlink was “one of the last remaining specialist PAS providers” servicing the UK National Health System (NHS) with their flagship product, Patient Case System, which was recognized as “a flexible, cost-effective [system] that can easily integrate with other clinical systems to support a ‘specialist modular system’ approach, enabling the benefits of a full [electronic patient record] without single supplier lock-in”.
The company said that Silverlink had long-standing customer relationships with 12 NHS Trusts with 11 of those Trusts new for Alcidion and one an existing user of its Miya systems, taking it to 38 Trusts about 26 percent of the acute NHS market. Alcidion said that about 95 percent of Silverlink’s revenue was recurring with Silverlink management forecasting revenue for the year to April 30, 2022 of $7.8 million and earnings before interest, taxation, depreciation and amortization (Ebitda) of $4.8 million.
Alcidion managing-director Kate Quirke said that “combining Miya Precision with Silverlink … will support the open availability of data to ensure our healthcare systems are well equipped to address the challenges ahead”.
Alcidion was in a trading halt and last traded at 32 cents.

ACTINOGEN MEDICAL

Actinogen says it will supply Xanamem and trial design support to an Oxford University 40-patient, 12-week, placebo-controlled trial for mild autonomous cortisol secretion.
Actinogen said the UK Medical Research Council-funded trial, would be led by the Oxford Centre for Diabetes, Endocrinology and Metabolism’s Prof Jeremy Tomlinson and evaluate the effects of Xanamem on bone density, metabolism, and cognitive function.
The company said that the collaboration was with researchers at Oxford’s Radcliffe Department of Medicine, with trial results expected in 2024.
Actinogen said that mild autonomous cortisol secretion was associated with over-production of the stress hormone cortisol by non-cancerous growths on the adrenal glands.
Actinogen managing-director Dr Steve Gourlay said the trial was “an important opportunity to investigate the potential benefits of Xanamem on the cortisol system outside of the brain”.
Actinogen was up one cent or 8.7 percent to 12.5 cents with 15.6 million shares traded.

VICTORIA GOVERNMENT, COMPUMEDICS

The Victoria Government says it is supporting Melbourne's Compumedics to establish a local manufacturing base for its Somfit wearable sleep and vital signs brain monitor.

In a media release from the Minister for Industry Support and Recovery Martin Pakula, the Government said that its support for the project had "helped Compumedics establish automated production lines at its Abbotsford base, allowing the company to expand its sophisticated medical device manufacturing operations", resulting in 33 new jobs over three years and targeting "an estimated export market value of $60 million over five years".

Compumedics executive director David Lawson told Biotech Daily that the amount of Victoria Government support was "commercial in confidence".

The State Government said that Somfit was a cloud-based patient monitoring system worn on the forehead, chest and wrist that remotely monitors sleep and medical conditions.

Previously, Compumedics said that it was exploring the application of Somfit to Covid-19 patients (BD: Aug 26, 2021),

The Government said that after a decade of manufacturing most of its products overseas, Compumedics had begun manufacturing its Somfit medical-grade monitoring device at its Abbotsford headquarters and would ramp-up production in the new year.

Mr Pakula said the investment "demonstrates Victoria's strengths as a key advanced manufacturing destination".

"We're supporting Victorian [medical technology] companies to grow and thrive because they can play a crucial role in driving our economic recovery and creating new jobs," Mr Pakula said.

Compumedics chair Dr David Burton said Somfit was the "result of 30 years of product and technology innovation and development and will help transform the way we monitor our health".

"We are grateful for the support of the Victorian Government to help bring this vision to life as we expand our global presence and create high-quality employment opportunities right here in Victoria," Dr Burton said.

Compumedics was unchanged at 36 cents.

RECCE PHARMACEUTICALS

Recce says its phase I/II trial of R327 clears all burn wound infections within seven days and the interim results are "in-line with reaching clinical trial end-points".

In July, Recce said it had begun dosing the first of 30 patients with infected burns in a phase I/II safety and efficacy trial of a spray-on formulation of R327 at Perth's Fiona Stanley Hospital (BD: Feb 16, Jul 12, 2021).

Today, the company did not state how many patients had been treated.

Recce said that in all patients treated with its synthetic anti-infective R327, visible infection reduction had been seen in under 24 hours with all acute infections cleared within five days, and chronic infections cleared within seven days, across gram-positive, gram-negative, multi-drug resistant, and biofilm categorized infections.

The company said that "as a result, clinicians have adopted a significantly shorter five-day treatment protocol", which originally was 14 days of treatment.

Recce said that target patient enrolment and treatment was expected in "early 2022".

Recce was up 7.5 cents or 8.7 percent to 93.5 cents.

IMUGENE

Imugene says the first patient in its phase I, single-centre, dose-escalation study of oncolytic virotherapy candidate Checkvacc has cleared the 28-day safety window.
In October, Imugene said that it had dosed its first of up-to 12 patients in the trial of CF33, now called Checkvacc, for triple negative breast cancer (BD: Oct 20, 2021).
The company said at that time that the study would evaluate the safety and initial evidence of efficacy of intra-tumoral administration of CF33 combined with a humanized sodium-iodide symporter (hNIS) and an anti-programmed death-ligand 1 (CF33-hNIS-anti PDL1) antibody, or Checkvacc, for metastatic triple-negative breast cancer.
Today, Imugene said that as a result of the patient clearing the safety window, the trial, titled 'A Phase I Study of Intra-tumoral Administration of CF33-hNIS-antiPDL1 in Patients with Advanced or Metastatic Triple Negative Breast Cancer', had dosed its second patient.
Imugene managing-director Leslie Chong said: "As this is our first oncolytic viro-therapy in the clinic, it's great to have no safety issues thus far with our first patient.
"We are very pleased to see our second patient joining the trial immediately following the [US Food and Drug Administration] specified 28-day stagger between patient dosing," Ms Chong said.
Imugene was up half a cent or 1.05 percent to 48 cents with 31.4 million shares traded.

ANTERIS TECHNOLOGIES

Anteris says Evolution Capital has fully underwritten the exercise of 1,830,843 listed options exercisable at $8.00 each by December 18, 2021, to raise $14,646,744.
Anteris said that with sub-underwriters L1 Capital and Regal Funds Management, Evolution had committed to take all entitlements attached to any potential shortfall.
The company said that the funds would be used for further development and clinical activities for its Duravr aortic heart valve and its Comasur transfemoral delivery system.
Anteris said Evolution would management and underwritings fees totalling six percent, and 75,000 options exercisable at $10.00 each by 24 December, 2024.
Anteris was up 10 cents or 1.2 percent to $8.50.

STARPHARMA

Starpharma says it has signed a research agreement with Roche Group's Genentech for its dendrimer-enhanced product (DEP) drug conjugates.
Starpharma previously said that its dendrimer-enhanced product used conjugates to enhance drug concentration at the disease site and reduce off-target toxicity to improve therapeutic outcomes for patients (BD: Aug 9, 2017).
The company said it had DEP agreements with Astrazeneca, Merck & Co, Chase Sun and "several undisclosed partnerships".
Starpharma was up 5.5 cents or 4.8 percent to $1.20 with 932,274 shares traded.

VGI HEALTH TECHNOLOGIES

VGI says it has filed a patent application to IP (intellectual property) Australia covering the delivery of its drug candidates for liver and pancreatic diseases.
VGI said that if granted, the patent, titled 'Transmucosal delivery of tocotrienols' would protect its intellectual property until 2041, with protection sought under the Patent Cooperation Treaty.
On the National (Newcastle) Stock Exchange VGI was untraded at 25 cents.

ORTHOCELL

Orthocell has requested a trading halt pending “an announcement in relation to Ortho-ATI randomized study results”.
Trading will resume on December 9, 2021 or on an earlier announcement.
In August the company said the last of 30 patients with rotator cuff tendinopathy and tear had completed their 12-month follow up visit (BD: Aug 31, 2021).
Orthocell last traded at 51.5 cents.

EPSILON

Epsilon has requested a trading halt “pending the completion of a capital raising, proposed to be led by CPS Capital Group Pty Ltd”.
Trading will resume on December 9, 2021 or on an earlier announcement.
Epsilon last traded at 10 cents.

CLARITY PHARMACEUTICALS

Clarity says that 6,642,100 shares will be released from ASX escrow on December 15, 2021.
Clarity said that following the release of the shares, it would have 178,359,266 shares issued on the ASX, with 112,562,712 shares available for trading, with a further 77,773,280 shares held in ASX escrow and 65,796,554 held in voluntary escrow for six months from its August 2021 listing date.
Clarity fell 1.5 cents or 1.8 percent to 83.5 cents.