Biotech Daily

Wednesday December 4, 2019

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PRESCIENT UP 20.5%; ORTHOCELL DOWN 9%**

*** CSL R&D SPEND UP, NEW ASTHMA DRUG TRIAL, PIPELINE**

*** ORTHOCELL $13m PLACEMENT, SHARE PLAN FOR $5m MORE**

*** PAINCHEK CONFIRMS $5m FEDERAL GRANT**

*** G MEDICAL $30m GEM GLOBAL DRAW DOWN EQUITY FACILITY**

*** AVECHO TO MARKET 6 TPM DRUGS**

*** ZELIRA (ZELDA) TAKES HOPE FOR AUTISM TO LOUISIANA**

*** THC SOUTHPORT FACILITY 1st MEDICAL MARIJUANA**

*** OSTEOPORE APPOINTS JACK O'MAHONY BOARD ADVISOR**

MARKET REPORT

The Australian stock market fell 1.58 percent on Wednesday December 4, 2019, with the ASX200 down 105.8 points to 6,606.5 points.

Ten of the Biotech Daily Top 40 stocks were up, 20 fell, eight traded unchanged and two were untraded. All three Big Caps fell.

Prescient was the best, up 1.7 cents or 20.5 percent to 10 cents, with 31.9 million shares traded. Kazia climbed 5.7 percent; both Cyclopharm and Universal Biosensors improved 4.8 percent; Antisense and LBT were up more than three percent; Volpara rose two percent; Avita was up 1.7 percent; with Paradigm and Pro Medicus up by less than one percent.

Orthocell led the falls, down five cents or 8.85 percent to 51.5 cents, with 4.6 million shares traded. Opthea lost 7.7 percent; Immutep was down six percent; Dimerix, Optiscan and Patrys fell more than four percent; Cynata and Polynovo were down more than three percent; Alterity, Clinuvel, Cochlear, Compumedics, Genetic Signatures, Impedimed, Medical Developments and Neuren shed two percent or more; Mesoblast, Nanosonics, Next Science, Starpharma and Telix were down more than one percent; with CSL and Resmed down by less than one percent.

CSL

CSL research and development head Dr William Mezzanotte says investment continues to increase and the company is building on its leadership in plasma therapies.

Dr Mezzanotte told the 2019 research and development briefing that CSL was identifying "emerging new medicines from both within its existing portfolio of plasma-derived products and through newer platforms such as gene and cell therapies and recombinant proteins".

Dr Mezzanotte said that in the year to June 30, 2019,CSL invested $US832 million ($A1,217.7 million) into its research and development portfolio, or 9.7 percent of total revenues.

He said that CSL had "forged targeted innovation partnerships in close proximity to its research and development locations, including at Melbourne's Bio21 Institute, the Bern-based Swiss Center for Translational Medicine and the Philadelphia, Pennsylvania-based University Science Center.

"Our phase III clinical program targeting the reduction of early recurrent cardiovascular events in heart attack survivors, CSL112, continues to track well," Dr Mezzanotte said.

"We continue our focus on developing new medical indications for immunoglobulins while improving manufacturing efficiencies across our plasma product portfolio," Dr Mezzanotte said.

CSL said that CSL311 was a new subcutaneous injection monoclonal antibody targeting multiple inflammatory agents involved in various diseases and had been selected as a treatment for asthma

The company said that CSL311 had advanced to a phase I, first-in-human trial for patients with mild to moderate asthma and it was hoped that asthma sufferers could self-administer CSL311 at home once every two to four weeks, acting prophylactically to prevent asthma attacks.

CSL said that CSL311 was "the first monoclonal antibody to simultaneously target three cell-signaling cytokines, or molecules, responsible for the immune response that causes asthma and in doing so, suppresses inflammation of airways".

The company said that Hizentra, a subcutaneous immunoglobulin product for chronic inflammatory demyelinating polyneuropathy (CIDP) as well as primary and secondary immunodeficiencies was in a phase III trial for the severe muscle disease, dermatomyositis.

CSL said that dermatomyositis was one of a group of acquired muscle diseases called inflammatory myopathies which were characterized by chronic muscle inflammation accompanied by muscle weakness.

The company said that if the disease was untreated it could lead to difficulty in walking or the need for a wheelchair or even becoming bedridden.

"Our pipeline is as robust and promising as ever," Dr Mezzanotte said.

"Our research and development portfolio holds the potential to unlock a broad range of new therapies for people with challenging medical conditions," Dr Mezzanotte said.

"That promise is what drives our 1,700-plus scientists to work every day as if someone's life depends on it, because it really does," Dr Mezzanotte said.

CSL said its therapeutic areas included immunology, neurology, haematology, thrombosis, respiratory, cardiovascular, metabolic, transplants and influenza vaccines.

The company said it used therapy platforms including plasma fractionation, recombinant technologies, cell and gene therapies and both cell-based and egg-based adjuvants.

CSL said that in 2019 it had launched for both Hizentra and Privigen for chronic inflammatory demyelinating polyneuropathy in Japan, as well as the influenza vaccines Flucelvax in Europe and Afluria in Australia.

CSL fell 71 cents or 0.3 percent to $277.19 with 932,553 shares traded.

ORTHOCELL

Orthocell says it has commitments for a $13 million placement at 50 cents a share and hopes to raise a further $5 million in an underwritten share plan at the same price.
Orthocell said the placement and plan price was an 11.7 discount to the 15-day volume weighted average price of 56.6 cents a share and eligible shareholders would be able to acquire up to $30,000 of new shares in the share plan.
Orthocell said the record date for the share plan was December 3, 2019, and the offer would open on December 6 and close on December 23.
The company said the funds would be used to accelerate regulatory approvals, to commercialize Celgro for bone, tendon and nerve regeneration, to develop and commercialize its Ortho-ATI (autologous tenocyte implantation), for business development, marketing and general working capital.
Orthocell said Bell Potter was the lead manager to the placement.
Orthocell fell five cents or 8.85 percent to 51.5 cents with 4.6 million shares traded.

PAINCHEK

Painchek says its $5 million Federal Government national trial grant with the Department of Health has been signed.
In April, Painchek said it had a grant from the Federal Government to licence its pain recognition computer application to more than 1,000 residential aged care providers and their 100,000 residents living with dementia for one year (BD: Apr 29, 2019).
Today, the company said the grant would allow it to conduct a national trial of its pain identification smart phone application on Australian dementia patients living in residential aged care facilities.
Painchek said the grant would provide access to patients in residential aged care, would allow it to collect relevant data on the use of Painchek in practice and to evaluate the efficacy of Painchek for the diagnosis and management of pain, quality of life and other health outcomes.
The company said the grant included payments of $500,000 on execution of the agreement to develop training materials and an evaluation report, $4.4 million for 100,000 licences for dementia patients in residential aged care and $100,000 for the delivery of an evaluation report at the end of the contract term, on December 31, 2019.
Painchek fell half a cent or 2.3 percent to 21 cents with 11.0 million shares traded.

G MEDICAL INNOVATIONS

G Medical says it has a three year, $30 million draw down equity facility with the Luxembourg-based Gem Global Yield LLC SCS.
G Medical said the facility would be capped at 1,000 percent of the average daily number of shares traded for the 15 days prior to the draw down notice.
The company said the subscription price would be 90 percent of the higher of either the average closing bid price of shares over the pricing period or a fixed floor price.
G Medical said it would pay $440,000 to Gem for the agreement and would issue 25 million options, exercisable at 26.5 cents each by November 29, 2024.
The company said 12.5 million of the options would be issued immediately.
G Medical said the funding would allow it to expand its sales force in the US and global markets, with 20 sales representatives hires in 2020 and a total of 60 by 2022, in order to capitalize on multiple opportunities.
G Medical was unchanged at 10 cents with 1.5 million shares traded.

AVECHO BIOTECHNOLOGY (FORMERLY PHOSPHAGENICS)

Avecho says it hopes to market a tocopheryl phosphate mixture reformulation of Daptomycin, Propofol, Phytonadione, Tacrolimus, Melphalan and Clopidogrel.

Avecho said its tocopheryl phosphate mixture (TPM) was a proprietary combination of two forms of phosphorylated vitamin E which improved drug solubility and stability to enhance injectable products.

The company said its TPM had an excellent safety profile and was manufactured in its Melbourne facility.

Avecho said it would use TPM to reformulate Daptomycin, an antibiotic for systemic, life-threatening infections; Propofol, a general anaesthetic used during surgery; Phytonadione or vitamin K for prophylaxis or to prevent blood clotting disorders; Tacrolimus, an immunosuppressant to lower the risk of blood transplantation rejection; Melphalan, a chemotherapy drug used to treat a variety of cancers; and Clopidogrel, an oral medication for heart attack and stroke.

Avecho was unchanged at 0.4 cents.

ZELIRA THERAPEUTICS (FORMERLY ZELDA THERAPEUTICS)

Zelira says it expects to expand its Hope medical marijuana franchise for autism spectrum disorder to Louisiana through a licencing deal with Advance Biomedics LLC.

In October, Zelda said it intended to merge with Ilera Therapeutics to form Zelira Therapeutics and to grant it access to the Hope portfolio (BD: Oct 9, 2019).

Last month, Zelda said Ilera planned to launch its Hope products in multiple US states and globally from early 2020 (BD: Nov 20, 2019).

Today, Zelira said its proprietary Hope formulations were launched in Pennsylvania in May 2019 by Ilera, which held the licence and since merged with Zelda.

The company said the commercial terms of its Louisiana licence were confidential.

Zelira was unchanged at 6.5 cents.

THC GLOBAL GROUP (FORMERLY THE HYDROPONICS GROUP)

THC says its Southport, Gold Coast, Queensland-based marijuana facility has completed the first farm-to-pharma processing and production of medical marijuana.

On Monday, THC requested a trading halt pending an announcement regarding “the completion of the first medicinal cannabis production at [its] Southport manufacturing facility” (BD: Dec 2, 2019).

Today, the company said its Canndeo brand would market medical marijuana medicines from the Southport facility, with an initial launch of a schedule four cannabidiol oral liquid medicine and additional cannabidiol-tetrahydrocannabinol products in 2020.

THC chief executive officer Ken Charteris said the company’s “medicinal cannabis team have achieved a major milestone today both for the company and for the Australian medicinal cannabis industry by producing our first farm-to-pharma medicinal cannabis at our Southport facility, in advance of our commercial scale launch next year”.

THC was up two cents or 5.4 percent to 39 cents.

OSTEOPORE

Osteopore says it has appointed Jack O'Mahony as a board advisor effective from today on an equity-based remuneration package.

Osteopore said Mr O'Mahony had four decades of medical device experience and was previously the president and chief executive officer of Cochlear.

The company said Mr O'Mahony was previously Asia Pacific president of Synthes, president of Howmedica, international president of Stryker Corp and international division president of Signature Orthopeadics.

Osteopore was up five cents or 6.7 percent to 80 cents.