Biotech Daily

Monday May 8, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PSIVIDA UP 17%, PRANA DOWN 5%**

*** UNIVERSAL BIOSENSORS, SIEMENS US BLOOD ANALYZER SALES**

*** BOTANIX BEGINS PHASE Ia CANNABIDIOL BTX-1503 FOR ACNE STUDY**

*** SIMAVITA COMPLETES $1.5m PLACEMENT**

*** CHIESI TO DISTRIBUTE PHARMAXIS BRONCHITOL FOR CF IN ITALY**

*** UNIVERSITY OF KANSAS JOINS PRESCIENT PTX-200 AML TRIAL**

*** RESAPP REQUESTS 'HUMANITARIAN PARTNERSHIP' TRADING HALT**

*** ADALTA: AD-114 SCALABLE, POTENTIAL FOR WET AMD**

*** RHINOMED SIGNS AMCAL, GUARDIAN FOR MUTE NASAL PLUGS**

*** GI DYNAMICS: RICARDO COHEN, CHRISTOPHER THOMPSON ADVISERS**

MARKET REPORT

The Australian stock market recovered 0.59 percent on Monday May 8, 2017 with the ASX200 up 34.3 points to 5,870.9 points.

Eighteen of the Biotech Daily Top 40 stocks were up, 15 fell, six traded unchanged and one was untraded. All three Big Caps were up.

Psivida was the best, up 38 cents or 17.1 percent to $2.60, with 7,224 shares traded.

Benitec climbed 8.8 percent; Bionomics and Compumedics improved more than six percent; Living Cell, Polynovo and Sirtex were up more than four percent; Neuren and Prima were up three percent or more; Cyclopharm and Mesoblast rose more than two percent; Acrux, Avita, ITL, Nanosonics and Universal Biosensors were up more than one percent; with Cochlear, CSL, Medical Developments, Opthea and Resmed up by less than one percent.

Prana led the falls, down 0.3 cents or 5.2 percent to 5.5 cents with 178,754 shares traded.

Ellex lost 4.9 percent; Factor Therapeutics and Starpharma were down more than three percent; Genetic Signatures, Impedimed and Uscom shed more than two percent; Actinogen, Admedus, Airxpanders, Atcor, Orthocell, Osprey and Reva were down more than one percent; with Pro Medicus down 0.9 percent.

UNIVERSAL BIOSENSORS

Universal Biosensors says that Siemens Healthineers has begun US sales of their co-developed Xprecia Stride Coagulation Analyser (BD: Sep 9, 2011).

Universal Biosensors said that the Analyser was a handheld device which delivered “fast, reliable prothrombin time international normalized ratio testing for point-of-care monitoring and management of oral anti-coagulation therapy with warfarin, a vitamin K antagonist”.

The company said that the Analyser received US Food and Drug Administration clearance last year (BD: Oct 5, 2016).

Universal Biosensors executive chairman Andrew Denver said that US sales was “an important milestone in our collaboration with Siemens”.

“Siemens is responsible for the sales and marketing and the global roll-out of the Xprecia Stride whilst [Universal Biosensors] is responsible for the manufacture of the strips,” Mr Denver said.

Universal Biosensors was up half a cent or 1.2 percent to 42 cents.

BOTANIX PHARMACEUTICALS

Botanix says it has begun a phase Ia study of the Permetrex-delivered synthetic cannabidiol BTX-1503 for acne.

Botanix said the phase Ia study would be conducted by the Berghofer Queensland Institute for Medical Research over the coming weeks, with data expected by the end of June 2017.

The company said that supporting data suggested BTX-1503 might inhibit the excessive production of oil in the skin, which was a primary cause of acne, as well as potentially reducing inflammation and bacterial infection.

Botanix executive director Matt Callahan said the study was designed to provide safety, dosing and pharmacokinetic data for BTX-1503 “to support the pilot acne patient trial, which will follow soon after study completion”.

The company said that prescription acne products generated more than $US4.5 billion in annual sales and was the most common skin disorder in the US affecting 40 to 50 million Americans.

Botanix said that acne had multiple pathogenic pathways including the over-production of oils, inflammation and bacterial infection and the only approved product that had an effect on oil production also carries significant side effects, including birth defects, lymphoma and suicide risks.

The company said that BTX-1503 was expected to have a superior side effect profile, based on the published clinical data for cannabidiol in other disease indications.

Botanix was unchanged at 5.1 cents with 1.1 million shares traded.

SIMAVITA

Simavita says it has raised $1.5 million in a placement to institutional and sophisticated investors at four cents a share.

Last week, Simavita said it hoped to raise the $1.5 million in the placement with an additional $1.43 million to be raised in a non-renounceable, one-for-seven rights issue at the same price, with Lodge Corporate underwriting the rights issue to $700,000 and Lodge Partners acting as the lead manager to the placement (BD: May 3, 2017).

Simavita fell 1.5 cents or 27.3 percent to four cents.

PHARMAXIS

Pharmaxis says that Chiesi Farmaceutici SpA will commercialize Bronchitol for cystic fibrosis in adults aged 18 years and over in Italy.
In 2014, Pharmaxis said the Parma, Italy-based Chiesi would fund up to $US22 million of a pivotal trial of Bronchitol for cystic fibrosis and signed a US distribution agreement, later extending it to German, the UK and Ireland (BD: Aug 4, 2014; Jan 18, May 8, 2015).
Today, the company said that Chiesi would take responsibility for the marketing, sales and distribution of Bronchitol with immediate effect.
Pharmaxis said that Italy had about 5,000 cystic fibrosis patients and was one of the top five European Union markets by value.
The company said that it manufactured Bronchitol for Chiesi on commercial terms and the two parties were in the final stages of extending the exclusive supply agreement to 2024 for these markets and the US.
Pharmaxis chief executive officer Gary Phillips said the company was “extremely pleased that Chiesi has sought to extend the number of European countries in which they distribute Bronchitol”.
The company said that Bronchitol was a spray-dried form of mannitol, delivered to the lungs by a specially designed, portable inhaler, and was approved for cystic fibrosis patients aged over six years in Australia and Russia and for patients aged 18 years and over throughout the European Union and in Israel.
Pharmaxis said that top-line results from a pivotal, phase III, US regulatory-directed clinical trial were expected by July 2017.
Pharmaxis was unchanged at 26.5 cents.

PRESCIENT THERAPEUTICS

Prescient says the University of Kansas Medical Centre will join its up to 18-patients phase Ib/II trial of PTX-200 for acute myeloid leukaemia.
In March, Prescient said it had completed the first cohort of three patients in its phase Ib trial of PTX-200 plus cytarabine for relapsed or refractory acute myeloid leukaemia treated with a dose of 25mg/m2 of PTX-200 given as a one hour intravenous infusion on day-1, day-8 and day-15 and in combination with 400mg/m2 of cytarabine as continuous infusion on day-2 to day-6 of each 21-day cycle, which demonstrated safety and no dose limiting toxicities (BD: Dec 14, 2016; Mar 8, 2017).
Prescient said at that time that the next dose level was 35mg/m2 of PTX-200.
Today, the company said it was dosing the second cohort at Florida’s H Lee Moffitt Cancer Center and expected to recruit its first patients at the Yale Cancer Center shortly.
Prescient chief executive officer Steven Yatomi-Clarke said that the Kansas City-based University of Kansas Medical Centre was located in the Midwest of the US which provided “geographical diversification for our recruitment”.
“Coupled with Moffitt and Yale, the study is well positioned to meet its patient recruitment target of enrolment completion this calendar year,” Mr Yatomi-Clarke said.
Prescient fell 0.3 cents or 3.1 percent to 9.3 cents.

RESAPP

Resapp has requested a trading halt “pending the release of an announcement regarding an update on the company’s partnership with a leading humanitarian organization”.
Trading will resume on May 10, 2017 or on an earlier announcement.
Resapp last traded at 30.5 cents.

ADALTA

Adalta says that its AD-114 could have efficacy for age-related macular degeneration and Lonza has shown the scalability of its yeast system I-body production.

Last year, Adalta chief executive officer Sam Cobb told Biotech Daily that the I-bodies platform was derived from human proteins that mimicked the shape of shark antibodies which came from a family of molecules called I-set, the intermediate group of immunoglobulin or immunoglobulin-like domains, with lead compound AD-114 selected for the treatment of idiopathic pulmonary fibrosis (BD: Jul 7, 2016).

Today, the company said that mice were treated with the anti-CXCR4 I-body AD-114 and had reduced lesion leakage and fibrosis when evaluated seven days after laser induced injury.

Adalta said that a poster, entitled 'Inhibition of the chemokine receptor CXCR4 reduces pathology in a laser induced mouse model of choroidal neovascularization' was presented at the Association for Research in Vision and Ophthalmology meeting in Baltimore, Maryland held from May 7 to 11, 2017.

The company said the project's aim was to evaluate the role of the chemokine receptor CXCR4 in a mouse model of choroidal neovascularization and the poster concluded that AD-114 "significantly altered TGF-beta signalling, cytokine signalling pathways and regulation of fibroblast proliferation".

The poster said that "overall, treatment with anti-CXCR4 I-body AD-114 may offer an alternative treatment mechanism than currently available with anti-VEGF agents".

Adalta said that age-related macular degeneration was treated with a range of anti-vascular endothelial growth factor (VEGF) inhibitors and although they had a profound effect on the acute pathology, in the longer term, vision loss continued for many patients.

The company said that new drugs were needed to treat wet age-related macular degeneration and one approach was to target cytokine signalling, which had been implicated in the development of neovascularization pathology.

Separately, Adalta said that that contract manufacturer Lonza has shown the scalability of its yeast system for the production of its I-bodies.

Adalta said that data on Lonza's XS Pichia yeast expression technology was presented at the Recombinant Protein Production conference in Dubrovnik, Croatia.

The company said that it began a collaboration with Lonza in 2014 to optimize the expression efficiency of an I-body in its XS Pichia system.

Adalta said that Lonza had been able to improve the host strains of Pichia to almost double the yield to about 7gm/L in half the fermentation time and the work showed the ability of the I-body platform to be expressed in an alternative system to the current standard bacterial system using Escherichia coli.

Adalta was up two cents or eight percent to 27 cents.

RHINOMED

Rhinomed says that Sigma Healthcare has advised that its Mute anti-snoring nasal plugs will be part of the 2017 core range for Amcal and Guardian pharmacies.

Rhinomed said the agreement added to its Sigma relationship, with the majority of Sigma's network of more than 700 pharmacies stocking the Mute devices.

The company said the Sigma product suite of trial pack, small, medium and large nasal plugs was available for order by more than 4,000 pharmacies in its distribution network.

Rhinomed said that the distribution was "a giant step in ensuring that Mute can become Australia's premier, front line solution for snoring and nasal congestion".

Rhinomed was unchanged at 18.5 cents.

GI DYNAMICS

GI Dynamics says it has appointed Dr Ricardo Cohen and Prof Christopher Thompson to its scientific advisory board.

GI Dynamics said that Dr Cohen was “a leader in the type 2 diabetes and obesity field” and had worked with the company’s Endobarrier duodenal insert.

The company said that Dr Cohen was the director of the São Paulo, Brazil-based Oswaldo Cruz German Hospital centre for obesity and diabetes, the former president of the Brazilian Society of Bariatric and Metabolic Surgery and the current president of the International Federation for the Surgery of Obesity and Metabolic Disorders, Latin America Chapter.

GI Dynamics said Dr Cohen had been the primary investigator for 15 studies, including two Endobarrier studies and had published more than 150 papers.

The company said that Prof Thompson was a gastroenterologist with experience in primary and revision procedures, had more than 200 academic publications to his name and had been the principal investigator in numerous clinical trials.

GI Dynamics said Prof Thompson was the director of therapeutic endoscopy at Brigham Women's Hospital, an associate professor of Medicine at Harvard Medical School in Massachusetts and the chair of the Association of Bariatric Endoscopy.

The company said that Dr Thompson held a Doctor of Medicine from Pennsylvania State University and a Master of Science.

GI Dynamics fell 0.1 cents or 1.5 percent to 6.4 cents.