Biotech Daily

Tuesday September 22, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PHARMAXIS UP 10%; ANALYTICA DOWN 14%**

*** PHARMAXIS, BOEHRINGER PXS4728A MEETS PHASE I ENDPOINTS**

*** TGA APPROVES BPH CORTICAL BRAIN ANAESTHESIA MONITOR**

*** OBJ REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** SIRTEX APPOINTS EX-AVCAL DR KATHERINE WOODTHORPE DIRECTOR**

*** GENETIC SIGNATURES APPOINTS PATRICK NOLAND US HEAD**

*** BIO-MELBOURNE ORPHAN DRUG, DEVICE REGULATION WORKSHOP**

MARKET REPORT

The Australian stock market climbed 0.74 percent on Tuesday September 22, 2015 with the ASX200 up 37.4 points to 5,103.6 points. Fifteen of the Biotech Daily Top 40 stocks were up, 12 fell, eight traded unchanged and five were untraded. All three Big Caps rose.

Pharmaxis was the best, up two cents or 9.8 percent to 22.5 cents, with 908,855 shares traded.

Oncosil climbed 7.1 percent; Benitec and Reva were up more than six percent; Biotron and Living Cell were up five percent or more; Medical Developments was up four percent; Acrux, Circadian, Cochlear, IDT, Mesoblast, Orthocell and Universal Biosensors rose more than two percent; with CSL, Resmed, Sirtex and Viralytics up less than one percent.

Analytica led the falls, down 0.1 cents or 14.3 percent to 0.6 cents with 341,435 shares traded.

Anteo, Atcor and Genetic Technologies fell more than four percent; Clinuvel and Ellex lost more than three percent; Actinogen shed 2.1 percent; Antisense, Impedimed and Prima were down more than one percent; with Bionomics and Nanosonics down by less than one percent.

PHARMAXIS

Pharmaxis says that the Boehringer Ingelheim acquired PXS4728A has met all its primary and secondary endpoints in its phase I trial for inflammatory diseases.

Pharmaxis said that Boehringer Ingelheim acquired PXS4728A to develop it as a treatment for cardio-metabolic diseases such as non-alcoholic steato-hepatitis or NASH.

Pharmaxis chief executive officer Gary Phillips told Biotech Daily that although there were no milestone payments attached to completing the phase I trial, there would be at the start of the phase II trial process.

In January, Pharmaxis began a two-part phase I trial of with an the initial single ascending dose study in 48 subjects, to be followed by a multiple ascending dose study in a separate group of 24 subjects (BD: Jan 21, Apr 7, 2015).

In May, Pharmaxis said that the Ingelheim, Germany-based Boehringer Ingelheim would pay an upfront fee of $39.2 million and potentially more than $750 million for PXS4728A for non-alcoholic steato hepatitis (BD: May 18, 2015).

Pharmaxis said at that time that PXS4728A which was a semicarbazide-sensitive amine oxidase vascular adhesion protein-1 (SSAO/VAP-1) inhibitor that worked by blocking leucocyte adhesion and tissue infiltration in inflammatory processes.

Today, the company said that following the April phase Ia single ascending dose positive results, the phase Ib multiple ascending dose trialled three oral daily doses ranging from 3mg to 10mg of PXS4728A over 14 days, which “was found to be safe and well tolerated”.

Pharmaxis said the data “confirmed the high oral bioavailability of PXS4728A and most importantly, showed these low doses are efficacious in inhibiting the enzyme and cause a long lasting inhibition suggesting PXS4728A can be dosed once a day”.

The company said that the positive phase I results enabled Boehringer Ingelheim to proceed with further development of the program.

Mr Phillips said that NASH was “becoming more prevalent and there is a clear need for more effective therapies”.

“PXS4728A inhibits an enzyme which has been highlighted in independent peer-reviewed publications as an excellent target to treat NASH and this first human trial of the drug confirms its strong pre-clinical profile translates into human studies,” Mr Phillips said.

“It is rare to be able to demonstrate effective target engagement in a phase I study so the fact that the long lasting enzyme inhibition seen in the phase Ia study was reinforced when given once a day for 14 days adds to our confidence in PXS4728A,” Mr Phillips said.

“We now look forward to the next value appreciating steps as the clinical development program proceeds with Boehringer,” Mr Phillips said.

Mr Phillips told an investor meeting in Melbourne today that the company had moved its focus to drug discovery for fibrosis and inflammation and had more products coming from its amine oxidase chemistry platform.

Mr Phillips said Bronchitol for cystic fibrosis was being marketed by commercial partners and the company would concentrate on taking drug candidates to phase II for partnering.

The University of Sydney’s Prof Jacob George said that about 30 percent of the world’s population apart, from sub-Saharan Africa and rural India, had fatty liver disease and the simplest intervention of diet and exercise was not being adopted.

Prof George said that obesity had led to liver fat and fibrosis in people aged over 60 years, but today children were obese and developing type 2 diabetes, implying that in 10 years there would be a significant increase in non-alcoholic steato-hepatitis and fibrosis.

Pharmaxis head of drug discovery Dr Wolfgang Jarolimek told the meeting that PXS4728A had a fast uptake, a half-life of less than two hours and was a long-lasting inhibitor of enzyme activity of more than 24 hours, and had no negative safety signals.

Pharmaxis was up two cents or 9.8 percent to 22.5 cents.

BPH ENERGY (FORMERLY BIOPHARMICA)

BPH says that the Australian Therapeutic Goods Administration has approved 3.89 percent investee company Cortical Dynamics' brain anaesthesia response monitor.
BPH said it had an option to increase its holding to more than 10 percent through the conversion of its secured loan.
The company said that TGA certification would allow Cortical to market the brain anaesthesia response (BAR) monitor in Australia and through the TGA's mutual recognition agreement enable Cortical to apply for Conformité Européenne (CE) mark approval to sell the BAR monitor in Europe.
BPH and Cortical said that the BAR monitor had "many significant sustainable competitive advantages" for patients, anaesthetists, hospitals and clinics, to reduce the risks associated with surgical procedures, increase levels of patient care, optimise the use of anaesthetic agents, increase efficiencies and reduce costs through a reduction in drug usage and a faster bed turn around in the theatre and post-operative recovery rooms around the globe.
The company said there were a number of electro-encephalogram (EEG) monitors commercially available, but one that was "reliably able to quantify the patient's anaesthetic state is still desperately needed".
BPH said that existing EEG-based depth of anaesthesia monitors were limited by their inability to monitor analgesic effects and they did not reliably measure all hypnotic agents.
In 2013, BPH said that a 25 patient study showed that the BAR monitor could distinguish between low and moderate doses of fentanyl (BD: May 6, 2013).
BPH was up 0.1 cents or 16.7 percent to 0.7 cents.

OBJ

OBJ has requested a trading halt "pending an announcement by the company in relation to a capital raising".
Trading will resume on September 24, 2015 or on an earlier announcement.
OBJ last traded at 6.3 cents.

SIRTEX MEDICAL

Sirtex has appointed former Australian Venture Capital Association chief executive officer Dr Katherine Woodthorpe as a non-executive director, effective from today.
Sirtex said that Dr Woodthorpe was an experienced non-executive director, serving on boards ranging from ASX listed companies to research institutions and government entities for more than 17 years.
The company said that prior to Avcal, Dr Woodthorpe had held a broad range of management and board positions, in Australia and overseas and had a knowledge of the private equity industry and the superannuation industry and a track record in technology industries including mining and healthcare.
Sirtex said that Dr Woodthorpe was described as "one of Australia's most influential people in innovation and has a track record for commercialisation".
The company said that Dr Woodthorpe held a Bachelor of Science from Manchester University and a Doctorate of Philosophy in chemistry.
Sirtex was up 15 cents or 0.45 percent to $33.55 with 160,279 shares traded.

GENETIC SIGNATURES

Genetic Signatures says Patrick Noland has been appointed US operations executive vice-president.

Genetic Signatures chief executive officer Dr John Melki said that Mr Noland had "decades of experience in the commercialization of advanced biological testing services … [which] are a perfect fit for our US strategy".

The company said that previously Mr Noland was the chief executive officer of the Lexington, Massachusetts-based anatomic pathology laboratory Stratadx and prior to Stratadx was with Laboratory Corporation of America for 17 years in sales roles.

Genetic Signatures said that Mr Noland held a Masters of Business Administration from Kennesaw State University in Georgia and a Bachelor of Science from the University of Georgia in Athens.

Genetic Signatures fell two cents or 4.1 percent to 47 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network's October 1, 2015 Workshop will explore orphan drug and device development regulatory strategies and commercial perspectives.

The Network said the 'Orphan Drug Development and Registration' workshop would discuss regulatory pathways, registration and marketing strategies, timelines and potential pitfalls in development and registration of medicines for rare conditions.

The Bio-Melbourne Network said that the importance of orphan drugs and devices to serve unmet clinical needs for rare diseases continued to increase, with considerable political support, as evidenced by about one-third of drugs approved by the US Food and Drug Administration in 2012 having orphan drug designation.

Bio-Melbourne Network chief executive officer Dr Krystal Evans said that "with nearly 200 new orphan drugs entering the development process each year, orphan drugs represent one of the fastest growing segments in the biopharmaceutical industry."

The Network said the speakers at the workshop included the Walsrode, Germany-based ERA Consulting founder and chief scientific officer, Dr Chris Holloway, Coté Orphan LLC principal and chief executive officer Dr Timothy Cote, Locus Consulting principal Michael Flood and ERA Consulting Brisbane-based director Dr Dianne Jackson-Matthews.

The Network said that participants would be able to learn hands-on approaches to and prepare for orphan drug applications.

The October 1, 2015 Workshop will be held at the Spring Street Conference Centre, 1 Spring Street, Melbourne with registration from 12.45pm for the workshop from 1pm to 5pm followed by a networking session.

To register go to: http://www.biomelbourne.org/events/view/383.