Biotech Daily

Wednesday November 9, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ATCOR UP 5%, VIRALYTICS DOWN 13%**

*** SUDA, EDDINGPHARM POTENTIAL $34m ZOLPIMIST INSOMNIA DEAL**

*** BLUECHIIP SELLS TRACKING KITS TO CHINA, EASTERN EUROPE**

*** UK NHS APPROVES MACH7 IMAGING PRODUCTS**

*** GI DYNAMICS GERMAN REGISTRY BACKS SAFETY, EFFICACY**

*** SG HISCOCK TAKES 6% OF RESONANCE**

*** CLINUVEL ROLLING US SCENESSE FOR EPP NDA IN 2017**

*** AVITA ADDS 2 SITES TO REGENERCELL DIABETIC FOOT ULCER TRIAL**

*** DR CHARLES DAY INNOVATION AND SCIENCE CEO; CRC ADVISORS**

MARKET REPORT

The Australian stock market tumbled 1.92 percent on Wednesday November 9, 2016 with the ASX200 down 101.2 points to 5,156.6 points.

Just four of the Biotech Daily Top 40 stocks were up, 31 fell, four traded unchanged and one was untraded. All three Big Caps fell.

Atcor was the best of the few, up 0.5 cents or five percent to 10.5 cents with 11,764 shares traded. Oncosil climbed 4.8 percent; Living Cell was up 1.3 percent; with Reva up 0.8 percent.

Viralytics led the falls, down 15 cents or 12.8 percent to $1.02 with 451,306 shares traded.

Dimerix lost 11.1 percent; Actinogen was down 10 percent; Orthocell fell 9.1 percent; Airxpanders, Opthea and Osprey retreated more than eight percent; Admedus, Neuren and Prana shed more than seven percent; Factor Therapeutics and Starpharma were down six percent or more; Ellex, IDT and Pro Medicus lost more than five percent; Genetic Signatures, Impedimed and Nanosonics fell more than four percent; Avita, Cyclopharm, Medical Developments, Mesoblast, Pharmaxis and Resmed were down more than three percent; Prima and Sirtex shed more than two percent; with Benitec, Bionomics, Clinuvel, Cochlear, Compumedics, CSL, Polynovo and Universal Biosensors down by more than one percent.

SUDA

Suda says that Macau's Eddingpharm will develop and commercialize its Zolpimist oral spray of zolpidem tartrate for insomnia in a potential $US26 million ($A33.9 million) deal.
Suda said that the Macau, China-based pharmaceutical company Eddingpharm (Asia) would be responsible for development, regulatory and commercialisation activities in China and once approved by the Chinese Food and Drug Administration, Zolpimist would be the first imported fast-acting oral spray of zolpidem tartrate available in China.
The company said it would receive $US300,000 ($A390,012) upfront and $US200,000 following registration in China and receive escalating tiered royalties on net sales in the territory, with a total deal value exceeding $US26 million based on Eddingpharm's forecast sales for the first 15 years from launch.
Suda said it would supply the product to Eddingpharm and both parties would work to maximize the commercial opportunity for Zolpimist in China.
Suda chief executive officer Stephen Carter said there was "a significant unmet need for insomnia patients, particularly patients that want rapid onset of sleep, have problems swallowing tablets or gastrointestinal complications".
"For these patients, Zolpimist offers an attractive treatment option with rapid absorption of the drug through the oral mucosa," Mr Carter said.
"We are delighted to have entered into this development and commercialisation agreement with Eddingpharm, an ideal partner for us in China," Mr Carter said. "They are a leading pharmaceutical company in the region and have an excellent track record in launching novel pharmaceutical products with experienced registration and market access professionals as well as an extensive sales and marketing team."
Eddingpharm chief executive officer Ni Xin said the orals pray had "demonstrated rapid absorption and onset of drowsiness in clinical trials".
"In China, it is estimated that more than 45 percent of the population, approximately 590 million people, have problems with sleep," Mr Ni said. "The demand … for chemical-based pharmaceuticals continues to grow strongly, hence, we are excited to have an exclusive license to this first-in-class FDA-approved treatment for insomnia."
"Zolpimist is an excellent fit with our current commercial infrastructure and our strategy for expanding our portfolio," Mr Ni said.
Suda was unchanged at 2.1 cents with 13.7 million shares traded.

BLUECHIIP

Bluechiip says it has sold three of its sample tracking starter kits including readers and 4,000 associated consumables to China and the Czech Republic.
Bluechiip said that one starter kit was sold through its China distributor to the Chinese Centre for Disease, Control and Prevention, an agency of the Chinese Ministry of Health based in Beijing, which was the second sale to the Centre.
The company said it sold two kits to the Prague-based subsidiary of the Bergamo, Italy-based European bio-bank product manufacturer and distributor Siad Group.
Bluechiip said that Siad-CZ would distribute the technology in Eastern Europe, with exclusivity in Czech Republic, Slovakia, Poland and Hungary and was "looking to collaborate with respect to sales and marketing".
Bluechiip chief executive officer Andrew McLellan said the starter kits were "the first step toward a successful rollout of our full suite of products," Mr McLellan said.
"Starter kits allow purchasers to become familiar with Bluechiip's technology and to train staff in their use," Mr McLellan said.
Bluechiip was up 0.2 cents or 5.4 percent to 3.9 cents with 1.1 million shares traded.

MACH7 TECHNOLOGIES

Mach7 says the UK National Health Service has approved supply of the full suite of its imaging software products.

Mach7 said that the NHS Supply Chain Framework lists organizations assessed to deliver products and services to the NHS, based on quality and commercial criteria and following a tender process evaluating vendors on financial criteria, clinical acceptability and ease of use, Mach7 was awarded the NHS Framework agreement.

The company said that inclusion on the Framework was required for all vendor products procured by NHS hospitals which managed 80 percent of all UK hospitals.

Mach7 said it would have unprecedented access to the UK healthcare market and reduced procurement times and costs to secure additional software licences.

Mach7 chief executive officer Albert Liong said that the UK healthcare market was “well-positioned to adopt the advanced enterprise imaging technology that Mach7 offers”.

Mach7 was up 0.4 cents or 10.3 percent to 4.3 cents with 2.2 million shares traded.

GI DYNAMICS

GI Dynamics says its German Endobarrier registry of 234 patients shows a 1.3 percent drop in HbA1c and weight loss of 15kg, or 29 percent of excess weight.

GI Dynamics said that the registry was conducted at the University Hospital Hamburg-Eppendorf and the hospital’s Dr Nina Riedel presented the data at the European Association for the Study of Diabetes, which held its meeting in Munich, Germany, from September 12 to 16, 2016.

The company said that its Endobarrier duodenal insert produced clinically relevant results, lowering mean absolute HbA1c blood sugar from 8.5 percent to 7.2 percent, lowering anti-diabetic medication in 78 percent of patients and reducing the injected dose of Insulin by 42 percent on a mean basis.

GI Dynamics did not specify when the data was collected in relation to the Endobarrier being inserted or typically removed after 12 months.

The company said that excess weight dropped by a mean of 15kg, which represented a 29 percent drop in excess weight, with a mean drop of 10cm in waist circumference.

GI Dynamics said that the safety profile was “clinically acceptable with a 1.7 percent event rate of hepatic abscess” or four of the 234 patients and a severe bleeding rate of 0.4 percent and all safety-related events were resolved with no long-term complications.

The company said that the German registry continued to expand with more than 300 patients to date.

GI Dynamics chief executive officer Scott Schorer said that the data from the German registry “continues to support the strong efficacy and safety profile of Endobarrier”.

GI Dynamics was up 0.2 cents or 10.5 percent to 2.1 cents.

RESONANCE HEALTH

SG Hiscock and Co says it has increased its substantial shareholding in Resonance from 21,016,635 shares (5.022%) to 25,868,854 shares (6.43%).

The Collins Street Melbourne-based SG Hiscock said the shares were held by HSBC Custody Nominees and gave its address as HSBC in Sydney.

The company said that it acquired 1,044,075 shares for $23,608 or 2.26 cents a share between November 2 and 8, 2016 but failed to disclose the cost of the other 3,808,144 shares as required under the Corporations Act.

Resonance fell 0.1 cents or 4.8 percent to two cents.

CLINUVEL

Clinuvel says it will submit a rolling “modular dossier” on Scenesse for erythropoietic protoporphyria to the US Food and Drug Administration during the first half of 2017.
Clinuvel said it met with the FDA’s Division of Dermatology and Dental Products on November 7, 2016 to discuss the content and format of a new drug application for Scenesse (afamelanotide 16mg) and after completion of the submission the FDA would observe a validation period of two months.
The company said that further interactions with the FDA would take place as the submission progressed and a positive benefit-risk assessment by the FDA would make the drug available as the first systemic photo-protectant for adult erythropoietic protoporphyria patients.
Clinuvel chief executive officer Dr Philippe Wolgen said the company “appreciates the formal discussion with the FDA”.
“We are fully aware that the dossier on a novel mode of action and first-in-class drug for a relatively unknown disease with a high impact on patients’ lives needs to be presented in a clear and cohesive manner,” Dr Wolgen said. “Our staff must now provide the FDA all further non-clinical and clinical data and convey comprehensive knowledge on the proposed treatment and planning for longer term follow-up of EPP patients.”
“One can merely hail the FDA’s recent progressive steps towards gaining a deeper understanding of EPP and the proposed treatment in an unmet medical need,” Dr Wolgen said. “For years to come this dossier could serve as a template for the development of other innovative drugs in the domains of photo-medicine and optical physics, as well as for diseases which are less well characterized or understood in medicine.”
Clinuvel fell 10 cents or 1.3 percent to $7.77.

AVITA MEDICAL

Avita says that London’s King’s College and Northwick Park Hospitals have joined its UK safety and efficacy trial of Regenercell spray-on-skin for diabetic foot ulcers.
In May, Avita said the first of 24 patients had been enrolled in the trial at Manchester Royal Infirmary, with London’s King’s College and Northwick Park hospitals to join shortly (BD: May 31, 2016).
Today, the company said that seven patients had been enrolled and were being treated at the Manchester Royal Infirmary and with three sites enlisted, enrolment could “proceed apace to recruit up to 24 patients” who would be followed over a 26-week evaluation period, with full enrolment expected “by early 2017”.
The company said that treatment would be assessed as an adjunct to standard-of-care treatments including debridement, cleansing, dressings and offloading, with key outcome measures of incidence of healing and rate of wound closure, as well as patient and physician satisfaction.
Avita said that Regenercell had Conformité Européenne (CE) mark and was approved for sale in the UK.
Avita chief executive officer Adam Kelliher welcomed the addition of the two London hospitals and said the company would gather health economics data.
“Everything about [diabetic foot ulcers] treatment is expensive,” Mr Kelliher said, “the daily dressing changes, the continuous attention needed throughout the public health system, and sadly, the significant surgery of amputation.”
“If we can break this cycle by closing the foot ulcers, we can improve the lives of many people and save a lot money,” Mr Kelliher said.
Avita fell half a cent or 3.85 percent to 12.5 cents with 1.3 million shares traded.

FEDERAL GOVERNMENT, INNOVATION AND SCIENCE AUSTRALIA

The Federal Government has appointed the University of Melbourne's Dr Charles Day as the chief executive officer of Innovation and Science Australia.

A media release from the Minister for Industry Innovation and Science Greg Hunt said that Innovation and Science Australia provided strategic, whole-of-government advice on all science, research and innovation matters including guidance on the $10.1 billion investment in 2016-'17 in innovation, science and research including measures through the National Innovation and Science Agenda.

The media release said that Dr Day was previously the University of Melbourne's Carlton Connect initiative program director and a member of the Murdoch Children's Research Institute board.

The media release said that Dr Day was previously the head of the University of Melbourne's technology commercialisation company, Melbourne Ventures, from 2004-'10 and was a co-founder of the Melbourne Accelerator Program supporting University start-ups.

The Federal Government said that Dr Day was a Rhodes Scholar and completed a Doctorate of Philosophy in the dynamics of jet engines at Oxford University.

Mr Hunt said that Prof Bronwyn Harch, Dr Rufus Black and Dr Bronte Adams had been appointed to the board of Innovation and Science Australia.

The media release said that Bellberry chief executive officer Kylie Sproston and Prof Christobel Saunders had been appointed to the Cooperative Research Centre advisory committee.