Biotech Daily

Wednesday July 6, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: NEUREN UP 10%, UNIVERSAL BIO DOWN 6%**

*** PSIVIDA WET AMD RABBIT STUDY TAKES DURASERT TKI TO CLINIC**

*** AVIRAGEN (BIOTA), GEORGIA STATE UNIVERSITY DEAL FOR RSV**

*** CLINUVEL WINS US SCENESSE FOR EPP FAST-TRACK STATUS**

*** DORSAVI SIGNS $250k US CONTRACTS**

*** REDHILL SIGNS GRUPO JUSTE IN SPAIN FOR RIZAPORT FOR MIGRAINE**

*** GOODBYE NUSEP, HELLO MEMPHASYS**

*** OTTO BUTTULA, WEBINVEST ABOVE 5% OF IMUGENE, AGAIN**

*** NANOSONICS APPOINTS EX-GE STEVEN SARGENT DIRECTOR**

MARKET REPORT

The Australian stock market fell 0.58 percent on Wednesday July 6, 2016 with the ASX200 down 30.5 points to 5,197.5 points.

Twelve of the Biotech Daily Top 40 stocks were up, 18 fell, eight traded unchanged and two were untraded.

Neuren was the best, up 0.6 cents or 10 percent to 6.6 cents with 2.3 million shares traded.

Genetic Technologies climbed 5.6 percent; Opthea was up 4.95 percent; Biotron was up 3.5 percent; Acrux, Benitec and Uscom rose more than two percent; with Airxpanders, Avita, Clinuvel, Ellex, Orthocell and Resmed up more than one percent.

Universal Biosensors led the falls, down two cents or 6.45 percent to 29 cents, with 62,556 shares traded.

Admedus, Antisense and Mesoblast lost more than six percent; Osprey fell 4.35 percent; Oncosil, Pro Medicus and Viralytics lost more than three percent; Impedimed, Living Cell Nanosonics and Sirtex shed more than two percent; Anteo, Medical Developments, Polynovo and Psivida were down more than one percent; with Cochlear, CSL, Reva and Starpharma down by less than one percent.

PSIVIDA CORP

Psivida says pre-clinical studies show that an injectable tyrosine kinase inhibitor is comparable to an approved biologic for wet age-related macular degeneration.

Psivida said that two studies in rabbits showed that the repurposed tyrosine kinase inhibitor (TKI) cancer drug “was comparably efficacious” to an injection of an approved biologic in both preventing choroidal neo-vascularization and reducing vascular leakage.

The company said it planned to advance toward clinical trials of the Durasert TKI insert for wet age-related macular degeneration, including toxicology studies necessary for an investigational new drug application.

Psivida chief executive officer Dr Paul Ashton said that the completion of the studies was “an exciting milestone in our development of a sustained-release treatment for wet [age-related macular degeneration] using our Durasert platform”.

Dr Ashton said that the most commonly used therapies for the disease targeted only vascular endothelial growth factor and required injections as frequently as monthly.

Dr Ashton said that blocking vascular endothelial growth factor (VEGF) alone did not result in long-term suppression of the disease and studies suggested that platelet-derived growth factor might play a role in age-related macular degeneration (AMD).

Dr Ashton said that the tyrosine kinase inhibitor used in the Durasert insert was known to block both VEGF and platelet-derived growth factor.

“Our goal is to effectively treat AMD on a sustained basis for six months with a single injection, targeting both VEGF and [platelet-derived growth factor] while avoiding the toxic systemic side effects of TKIs and the frequent injections of current … anti-VEGF biologics,” Dr Ashton said.

Psivida said that age-related macular degeneration was “the leading cause of vision loss in people over 65” and was most commonly treated with intra-vitreal injections of biologics that blocked the VEGF molecules that were a factor in the abnormal sub-retinal blood vessel growth leading to the disease.

Psivida said the leading treatments were the FDA-approved Lucentis and Eylea and the off-label use of the anti-cancer drug Avastin, which were all anti-VEGF biologics, which needed repeated injects into the eye and typically lost efficacy over time.

The company said that some TKIs, including the one used in this insert, were known to inhibit platelet-derived growth factor as well as VEGF, but the toxicity of oral TKIs for cancer prevented systemic use for age-related macular degeneration, and Durasert would deliver a dose to the retina about 1,000 times less drug than used in cancer therapy.

Psivida fell eight cents or two percent to $4.00.

AVIRAGEN THERAPEUTICS (FORMERLY BIOTA PHARMACEUTICALS)

Aviragen says it has a licence and research agreement with Georgia State University to develop and commercialize respiratory syncytial virus (RSV) replication inhibitors.

Aviragen said that the non-fusion inhibitor discovered by Georgia State University Institute for Biomedical Sciences Prof Richard Plemper and his team would complement its Melbourne-invented BTA585 fusion inhibitor.

The company said that Prof Plemper's research focused on clinically significant members of the myxovirus families such as influenza virus and respiratory syncytial virus and that by studying the molecular replication mechanism of the pathogens Prof Plemper’s laboratory developed innovative drug screening technologies for the identification and characterization of novel therapeutics.

Last night on the Nasdaq, Aviragen was up two US cents or 1.4 percent to $US1.42 ($A1.92, equivalent to 24 cents, before departing the ASX) with 5,517 shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says the US Food and Drug Administration has granted Scenesse fast track designation for erythropoietic protoporphyria.

Clinuvel said that the designation of Scenesse (afamelanotide 16mg) for erythropoietic protoporphyria (EPP) “recognises the severity of EPP and the unmet medical need of the disorder in the US”.

The company said that fast track designation was recommended following an initial FDA review of the Clinuvel data sets requested in early 2016 and enabled it to file a new drug application on a rolling basis for US regulatory assessment.

Clinuvel said that a meeting would be scheduled with the FDA to discuss the timing of the first filing of the scientific dossier, which was eligible for priority review, allowing an abbreviated review time of about six months.

The company said that Scenesse was granted FDA orphan designation for EPP in 2008, which meant lower filing fees and market exclusivity for seven years following first market access in the US.

Clinuvel said that it had received a large number of US patient requests to access Scenesse, which had to wait for regulatory approval; but there was “a strong network of expert EPP treatment centres in the US, coordinated by the US Porphyrias Consortium”.

Clinuvel chair Stan McLiesh said the fast track designation was “excellent news for US EPP patients, as Clinuvel has been in productive discussion with the US FDA for a considerable time directed towards making the drug available”.

“The FDA has shown the vision to first look at Clinuvel’s scientific data and agree to a swift review process and involve patients and expert physicians for a comprehensive meeting to learn more about the disease and the potential of the innovative treatment,” Mr McLiesh said.

Clinuvel acting chief scientific officer Dr Dennis Wright said he expected the FDA to ask Clinuvel to implement strict pharmaco-vigilance measures once the drug was available in the US, similar to the systems in place in Europe.

“We see increasing harmonization between [European Medicines Agency] and FDA when it comes to managing the risks of novel treatments made available to the public,” Dr Wright said. “The common regulatory thinking is reflected in an approval process where the voice of patients and physicians is given weight in decision making.”

“Clinuvel’s regulatory team is now being expanded to ensure that the [new drug application] dossier is to a high standard and that we move through this review process swiftly,” Dr Wright said.

Clinuvel was up seven cents or 1.6 percent to $4.40.

DORSAVI

Dorsavi says that in the last month it has signed US contracts for its wearable movement sensor system worth more than $250,000.

Dorsavi said that in partnership with the Woodland, Washington-based injury prevention company Workright NW it had secured two contracts valued at more than $230,000 and separately signed a contract with the US National Institute of Safety and Health to provide two sets of the Dorsavi movement sensors.

The company said that the Institute was part of the US Department of Health and Human Services Centers for Disease Control and Prevention, with a mandate to assure “every man and woman in the Nation safe and healthful working conditions and to preserve our human resources”.

Dorsavi fell half a cent or 1.6 percent to 31.5 cents.

REDHILL BIOPHARMA

Redhill says it has signed an agreement with Grupo Juste SAQF to commercialization Rizaport for migraine in Spain with the right of first refusal in other territories.
Redhill said that the 10-year agreement with the Madrid, Spain-based Grupo Juste included the Montreal, Quebec-based drug delivery company Intelgenx for the Rizaport oral thin film formulation of rizatriptan for acute migraines.
The company said that Grupo Juste had exclusive rights for Rizaport in Spain and a right of first refusal for Belize, the Carribean, Chile, Colombia, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Panama, the Middle East and Morocco.
Redhill said that it and Intelgenx were entitled to an upfront payment milestone payments and tiered royalties, but the specific terms were not disclosed.
The company said that Spain launch was expected by July 2017 and Rizaport had been granted German marketing authorization under the European Decentralized Procedure.
Redhill is developing a pipeline of drugs that includes three acquired from Sydney's Giaconda and RP101 which was being developed by Acuvax.
Last night on the Nasdaq, Redhill closed down 4.9 US cents or 0.45 percent at $US10.80 with 3,099 shares traded.

MEMPHASYS (FORMERLY NUSEP HOLDINGS)

The ASX has formally approved Nusep's name-change to Memphasys and the company has begun trading under the ASX code of MEM.
Memphasys was up 0.1 cents or 11.1 percent to one cent.

SIMAVITA

The Hong Kong-based Daniel Hegglin says he has become a substantial shareholder in Simavita with 16,800,000 Chess depository instruments (6.68%).
Mr Hegglin said the shares were held by HSBC Bank Australia and Morgan Stanley & Co with 12,000,000 CDIs acquired in the placement at five cents a share (BD: Jun 29, 2016).
Simavita was up 0.1 cents or 1.85 percent 5.5 cents.

IMUGENE

The Ashgrove East, Queensland-based Webinvest said it has returned to a substantial holding in Imugene with 86,800,000 shares (5.01%).
In June, Webinvest has reduced its holding in Imugene from 107,000,000 shares (6.18%) to 86,425,000 shares (4.99%)(BD: Jun 15, 2016).
Today, Webinvest director Otto Buttula said that between September 18, 2013 and July 5, 2016 Webinvest acquired 86,800,000 shares for $770,290 or 8.9 cents a share but did not disclose the cost of the 375,000 shares acquired between June 10 and July 5, 2016.
Mr Buttula resigned as an Imugene director on December 17, 2015.
Imugene was up 0.1 cents or 14.3 percent to 0.8 cents with 1.8 million shares traded.

NANOSONICS

Nanosonics says it has appointed Steven Sargent as a non-executive director.

Nanosonics said that Mr Sargent joined General Electric Capital in 1993 and was formerly the chief executive officer of GE Australia, New Zealand, Papua New Guinea and the Pacific and was the first Australian appointed to senior executive positions in the company.

The company said that prior to his retirement Mr Sargent was GE Mining chief executive officer.

Nanosonics said that Mr Sargent was currently a non-executive director of Origin Energy, the Great Barrier Reef Foundation and chairman of the Origin Foundation.

The company said that Mr Sargent held a Bachelor of Business from Charles Sturt University in New South Wales.

Nanosonics fell five cents or 2.2 percent to $2.25.