Biotech Daily

Tuesday December 2, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ONCOSIL UP 12%, OPTISCAN DOWN 16%**

*** SIENNA AT BIO21: 'FROM INCUBATION TO GRADUATION'**

*** MONASH LICENCES USE OF FENRETINIDE FOR DENGUE TO 60P**

*** NETHERLANDS APPROVES PSIVIDA'S ILUVIEN**

*** RHINOMED CLAIMS 75% MUTE SUCCESS FOR SNORING**

*** VIRALYTICS RECEIVES $2.5m FEDERAL R&D TAX REFUND**

*** NUSEP SELLS MINOMIC FOR $378k**

*** VIRAX BECOMES PRESCIENT, CODE CHANGE COMING**

*** SCINTILLA, TECHINVEST TAKE 6% OF AGENIX**

*** OBJ REQUESTS 'PRODUCT AGREEMENT' TRADING HALT**

*** MEDICAL AUSTRALIA APPOINTS COO DARRYL ELLIS CEO**

MARKET REPORT

The Australian stock market bounced back 1.41 percent on Tuesday December 2, 2014 with the S&P ASX 200 up 73.6 points to 5,281.3 points. Fifteen of the Biotech Daily Top 40 stocks were up, 11 fell, 12 traded unchanged and two were untraded.

Oncosil was the best, up one cent or 11.8 percent to 9.5 cents with 167,677 shares traded.

Bionomics climbed 8.05 percent; Tissue Therapies was up 5.6 percent; Atcor and Sirtex rose more than four percent; Analytica, Mesoblast, Osprey and Universal Biosensors were up more than three percent; Benitec, Cochlear, IDT and Psivida rose more than two percent; CSL, Nanosonics and Phosphagenics were up more than one percent; with Clinuvel and Resmed up by less than one percent.

Optiscan led the falls, down 0.9 cents or 16.1 percent to 4.7 cents with 4.2 million shares traded. Living Cell lost nine percent; GI Dynamics fell five percent; Anteo and Avita fell more than four percent; Biotron and Starpharma shed more than two percent; Ellex, Pharmaxis and Viralytics were down more than one percent; with Acrux down 0.4 percent.

BIO21, SIENNA DIAGNOSTICS

Sienna Diagnostics managing director Dr Kerry Hegarty has described her company's development from incubation at Bio-21 to the graduation of signing a partnering deal.

At the Bio21 Breakfast in Parkville entitled 'Incubation to Graduation. Nurturing start-ups to success: Sienna Cancer Diagnostics journey at Bio21', Dr Hegarty said that in 10 years her view of "success" changed from creating a return to investors to signing a partnering deal, to creating jobs to earning revenues and finally to "getting into the black".

Dr Hegarty said that Sienna had been developing cancer diagnostics based on using DNA telomerase as a proven cancer biomarker and as an adjunct to normal cytology.

Dr Hegarty said that her company's test simply took part of a patient's urine sample and applied the test "exploiting existing workflow practices".

She said that up to 25 percent of urine tests were "atypical", meaning that the laboratory was uncertain whether they were positive or negative and requiring further tests.

"The Sienna test meets that 20 to 25 percent unmet need," Dr Hegarty said.

Dr Hegarty said that Sienna began at the Bio21 incubator, adjacent to the Royal Melbourne Hospital in 2005 and began with a small capital raising, with subsequent raises of $3.5 million and $2.1 million, sufficient to conduct a 300-patient study.

She said that Sienna had its first commercial partner for reagents as well asa second partner which was described as "the largest path lab in the world" and a third agreement which was "at the term sheet stage", with first revenues expected by April 2015.

The University of Melbourne Department of Chemistry's Prof Tom Healy described how he became involved in a company called Technology Transactions which became Sienna Capital and eventually Sienna Diagnostics.

Prof Healy said that the company needed a chief executive officer and he knew Dr Hegarty who was then working in the Department of Geology and asked her if she would mind a small change in direction to running a cancer diagnostics company.

Prof Healy said that Government funding was important for start-up companies, which were "a huge risk" and those risks should not be minimized.

Prof Healy said that companies needed to think globally because the Australian market on its own was too small and any new diagnostic needed to be highly sensitive, novel and robust so it could be used anywhere by any company.

Prof Healy said that start-up companies needed to seek support, including cash from governments, industry and universities.

Bio21 director Prof Tony Bacic said that Bio21's mission was to be a bio-incubator, following the model set in Batavia, New York by Joe Mancuso.

Prof Bacic said that 15 percent of Bio-21 was used as a bio-incubator with half a dozen small to medium sized companies using the premises as a home.

"Industry engagement is not a tap you can turn on and off," Prof Bacic said. "It requires long term relationships."

Prof Bacic said that academia had learnt that discoveries needed translation.

Ausbiotech chief executive officer Dr Anna Lavelle told the breakfast the benefits of being small were the responsiveness and autonomy, offset by the lack of resources.

Dr Lavelle said that the large number of small companies meant the industry was not unionized and that meant it had a lack of power that the car industry had.

Dr Lavelle said that Australia was the fourth strongest country for biotechnology but the sector was "still not reaching goals".

Dr Lavelle said that Federal Government incentives were critical including the R&D Tax Incentive as well as treatment of employee shares schemes and said Ausbiotech was calling for the establishment of the 'Patent Box' system which reduced taxation on all income from intellectual property by up to 80 percent.

MONASH UNIVERSITY

Monash University says that it has licenced the use of potential cancer drug Fenretinide for dengue fever to 60P Australia.
Monash said that 60P Australia was a subsidiary of the Washington, DC-based 60° Pharmaceuticals.
The University said that more than one third of the world was at risk of the mosquito-transmitted dengue fever, with 96 million symptomatic infections each year, about 500,000 hospitalizations for dengue haemorrhagic fever and about 12,500 deaths and cost about $US12 billion a year.
Monash University said that treatment was either oral or intravenous rehydration for mild or moderate cases and intravenous fluids and blood transfusion for more severe cases.
Monash University said that its researchers, led by Prof David Jans, had developed a novel screening approach for identifying new classes of antiviral drugs and this had been used to identify Fenretinide as having potential for dengue fever.
“Our screening approach focuses on a specific interaction between a virus and its host during an infection,” Prof Jans said.
“This interaction is the critical point at which the virus accesses and takes over the control centre [or the nucleus] of the host cell,” Prof Jans said.
“This screening approach enables us to identify drugs that specifically target the virus in this interaction so we can stop it spreading the infection in the body,” Prof Jans said.
Prof Jans said the approach targeted at dengue virus made it possible to identify Fenretinide, previously investigated for use in cancer, as having potential to treat dengue.
According to the US National Cancer Institute website Fenretinide is “an orally-active synthetic phenylretinamide analogue of retinol (vitamin A)”.
“The discovery of Fenretinide as a dengue-focused antiviral drug validates the power of our novel screen to find new classes of drugs against such viruses,” Prof Jans said.
“We are excited about partnering our work with 60P and seeing this validation progress into the clinic and beyond,” Prof Jans said.
60P chief executive officer Dr Geoffrey Dow said that the company was “delighted to partner with an organization like Monash that shares our vision in taking first class research and translating it into new and affordable medicines that treat and prevent neglected diseases such as dengue”.
Monash Medicine Faculty senior business development manager Dr Michael Bettess said that the partnership had “the potential to benefit not only dengue fever patients but also people suffering from related viral infections and may lead to more research in drug discovery and development from our validated platform”.

PSIVIDA

Psivida says the Dutch Inspectie voor de Gezondheidszorg has granted marketing authorization to Iluvien for chronic diabetic macular oedema
Psivida said that the Netherlands approval for Iluvien, for vision impairment associated with chronic diabetic macular oedema considered insufficiently responsive to available therapies, was the fourteenth country to approve Iluvien for commercialization.
The company said that Iluvien was marketed in the UK and Germany and was scheduled to launch in Portugal this year, with marketing approval in 13 EU countries and pending approval in four others.
The company said it was entitled to 20 percent of the net profits from sales of Iluvien by its licencee Alimera Sciences on a country-by-country, quarter-by-quarter basis.
Psivida was up 13 cents or 2.6 percent to $5.10.

RHINOMED

Rhinomed says that topline results from an independent trial in snoring, sleep quality and night time nasal congestion demonstrated significant benefit from its Mute nasal plugs.
Rhinomed said that it had has submitted applications to the European, US and Australian regulatory authorities to allow the sale of the Mute technology.
The company said that the over-the-counter snoring, sleep quality and night-time nasal congestion market was a multi-billion dollar market with limited effective solutions.
Rhinomed said that the Mute nasal plugs were a nasal breathing aid designed to increase airflow and designed to alleviate the incidence and severity of snoring and improve sleep quality.
The company said that 79 percent of the subjects in the trial reported that their partners snoring affected their ability to get an uninterrupted night's sleep with 54 percent reporting that it had a high or extreme impact on their physical wellbeing and energy levels.
Rhinomed said that the independent in-home trial was carried out in November 2014 and was the first trial that assessed the impact of the Mute technology on the snoring and sleep quality of the snorer and the impact of this on their bed partner.
The company said that six percent of eligible subjects elected to discontinue because they objected to placing something in their nose.
Rhinomed said that 118 subjects aged 35 to 65 years and their partners were selected with diagnosed sleep apnoea patients screened out, as were those whose snoring emanated from their throat or lower airways and those whose body mass index placed them in a morbidly obese category.
The company said that snoring subjects were asked to assess their sleep quality before the use of the Mute technology and again during five days of continual use, along with partners completing an assessment of their sleep quality before and during the trial.
Rhinomed said that the end-points were measures across sleep quality, general wellbeing and sleep hygiene and responses to specific questions regarding competitive products.
The company said that it would publish and present a full analysis of the results at the consumer launch.
Rhinomed said that 75 percent of the snorer group reported a reduction in their snoring and 78 percent reported an improvement in their ability to breathe at night.
The company said that their 73 percent of their partners reported a significant reduction in snoring severity with 67 percent reporting a reduction in volume and with a 63 percent reduction in frequency and a 65 percent reduction in duration.
Rhinomed said that by day three of the trial 72 percent of subjects reported being comfortable with the product, with sleep quality scores improving in both the snorer and partner group.
Rhinomed chief executive officer Michael Johnson said that snoring affected millions of people world wide and had a "clear and undeniable impact on the sleep quality of snorers and their partners".
"The trial clearly and unequivocally shows that the Mute technology can improve the breathing of the snorer and that it may alleviate snoring," Mr Johnson said.
"This is genuinely exciting news for millions of couples who are awoken each night by snoring," Mr Johnson said.
"The trial results have exceeded our expectations and we look forward to receiving the appropriate approvals and registration advice from the relevant regulatory authorities," Mr Johnson said.
Rhinomed said that once approved the Mute plugs would be available online before a broader roll out through the pharmacy and grocery retail sector.
Rhinomed was up 0.1 cents or 3.7 percent to 2.8 cents.

VIRALTYICS
Viralytics says it has received $2,476,255 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Viralytics said the rebate related to research and development expenditure in its financial year to June 30, 2014.
The company said the funds would be used to progress development of its Cavatak clinical program.
Viralytics fell half a cent or 1.6 percent to 31.5 cents.

NUSEP
Nusep says it has sold its equity holding in Minomic International with the sale of shares returning $377,945.
Nusep executive chairman Alison Coutts said that “to focus our efforts on our core business of Spermsep, we have finalized the sale of shares in Minomic”.
Ms Coutts said that the proceeds would assist human in-vitro clinical trials of the Spermsep technology in Australian in-vitro fertilization centres and enable a bovine in-vitro fertilization study in Germany with our partner Minitüb GmbH.
“These studies will further validate the commercial advantages of the Spermsep technology for selecting sperm over current practice,” Ms Coutts said.
“The sale has been off the back of the recent announcement of the heads of agreement with Minitüb GmbH, a global leader in servicing the animal reproduction market,” Ms Coutts said.
“This agreement will allow us to work together to build the international sales of Spermsep sperm selection devices and consumables,” Ms Coutts said.
Nusep was untraded at five cents.

PRESCIENT (FORMERLY VIRAX HOLDINGS)
Prescient, which was formerly Virax, says it has formally changed its name and its ASX code will change to PTX on December 15, 2014.
Prescient was suspended for its 20-to-one consolidation and last traded at 14 cents.

AGENIX
Scintilla Strategic Investments and Techinvest Holdings have become substantial shareholders in Agenix with 7,925,000 shares or 6.05 percent of the company.
The Broadbeach Queensland-based companies, both of which Andre Marschke is a director, said that shares were bought and sold between May 21, 2013 and September 5, 2014 with the largest number of shares cited 10,507,437 shares or $201,000 or 1.9 cents a share.
Agenix was unchanged at 1.2 cents.

OBJ
OBJ has requested a trading halt “pending an announcement in relation to a product development and licencing agreement term sheet”.
Trading will resume on December 4, 2014 or on an earlier announcement.
OBJ last traded at 9.5 cents.

MEDICAL AUSTRALIA

Medical Australia says it has appointed chief operating officer Darryl Ellis as chief executive officer, effective immediately.

Medical Australia said that Mr Ellis joined the company in February 2014 as chief operating officer had been “instrumental in the integration of the Medivet subsidiary ... significantly lowering the cost base of the combined businesses”.

The company said that Mr Ellis had driven a program of restructure and rationalization which enabled a return to profitability.

Medical Australia was untraded at 7.1 cents.