Biotech Daily

Wednesday September 30, 2009

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH EVEN: NOVOGEN UP 13%; PSIVIDA DOWN 10%**

*** OPTISCAN TRIALS WORLD'S FIRST DUAL HIGH DEFINITION SCOPE**

*** RESONANCE DEVELOPS FASTER FERRISCAN RAPIDE LIVER TEST**

*** NOVOGEN'S NV-128 SAFE, HIGH ANTI-CANCER ACTIVITY IN MICE**

*** PSIVIDA HIGH DOSE STEROID INCREASES 18-MONTH EFFICACY**

*** US JAK2 PATENT FOR CYTOPIA; ASHLEY ARNOTT APPOINTED CFO**

*** LABTECH DEVELOPING NEW LABORATORY SOLUTION**

*** USCOM SHARE PLAN RAISES $1.1m**

*** OBJ REQUESTS 'STUDY RESULTS' TRADING HALT**

MARKET REPORT

The Australian stock market slipped 0.2 percent on Wednesday September 30, 2009 with the S&P ASX 200 down 9.5 points to 4743.6 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 15 fell, six traded unchanged and four were untraded.

Uscom was technically best, up 12 cents or 17.65 percent to 80 cents with 7,235 shares traded followed by Novogen up 8.5 cents or 13.2 percent to 73 cents with 492,150 shares traded and Labtech up 11 percent to 15 cents.

Bionomics climbed eight percent; Acrux, Genetic Technologies and Tissue Therapies were up more than five percent; Cytopia was up 4.35 percent; Biota and Chemgenex were up more than three percent; Prana and Sunshine Heart both rose 2.17 percent; with Circadian and Genera up more than one percent.

Psivida led the falls, down 57 cents or 10.3 percent to $4.95 with 6,639 shares traded, followed by Compumedics down two cents or 9.8 percent to 18.5 cents.

Benitec, Optiscan and Tyrian lost eight percent or more; Living Cell fell six percent; Antisense was down 5.7 percent; Phosphagenics fell four percent; Starpharma and Universal Biosensors shed more than two percent; with Mesoblast down 1.9 percent.

OPTISCAN

Optiscan says the first trial of its dual high definition second generation confocal endomicroscope has produced “crisp clear three dimensional cell level images”.
Optiscan said the first clinical use of the endomicroscope was conducted at Melbourne’s Francis Cabrini Hospital by gastroenterologist Prof Finlay McCrae.
The company said the second generation endoscope featured “a high definition confocal endomicroscope designed and built by … Optiscan”.
Optiscan said the endoscope combined “the benefits of the latest high definition endoscopic camera, which provides crisper and clearer images for finding suspicious tissue, with high definition endomicroscopy, a technology that provides three dimensional cell level detail and images akin to those previously only available from biopsy”.
Optiscan chief executive officer Vicki Tutungi said the company was “delighted with these results from our generation two endomicroscope”.
“We have already shown with our first generation technology … that when the microscope is used in a standard definition endoscope, a doctor can identify more disease by observing cellular detail in real-time - not days later, when the pathology lab has processed a biopsy,” Ms Tutungi said. “But the standard definition video does not easily reveal all of the possible areas that could be interrogated with the microscope, a limitation now solved by putting the latest miniature [high definition] camera alongside the latest [high definition] endomicroscope scanner.”
“This combination addresses the two key steps of an endoscopic examination - firstly to find suspicious tissue and then to identify exactly what it is and whether it should be biopsied or treated,” Ms Tutungi said.
“Since we first introduced endomicroscopy, endoscopists have told us this combination would be their dream endoscope - with this achievement, ‘double HD’ is now a reality,” Ms Tutungi said.
Optiscan said it would focus on building prototypes for the key opinion leaders around the world.
Optiscan fell one cent or 8.3 percent to 11 cents.

RESONANCE HEALTH

Resonance says its Ferriscan Rapide will reduce the magnetic resonance imaging (MRI) time required for Ferriscan liver tests by 60 percent.
Resonance said the reduced time would be “a significant benefit to patients and to radiology departments using the Ferriscan test”.
The company said the time reduction with Ferriscan Rapide would not impact on “the accuracy and precision” of the system but would deliver “a significant cost savings to MRI departments and patients”.
The company said that a 60 percent reduction in scan time to 10 minutes would make the test more accessible to paediatric patients who previously required sedation.
Resonance said London’s Whittington Hospital was the first medical site to provide Ferriscan Rapide and the Whittington’s imaging services manager Recep Suleyman said the Ferriscan Rapide replaced “the need for liver biopsy in many cases … [providing] a valuable clinical tool for consultants to manage iron levels in their patients”.
Resonance said the UK was a significant market for Ferriscan with a large population of patients with iron overload and a springboard to the European market.
The company said the new Ferriscan Rapide was “a significant step forward in our global rollout of Ferriscan making the test more affordable for patients”.
Resonance fell 0.1 cents or 6.25 percent to 1.5 cents.

NOVOGEN

Novogen subsidiary Marshall Edwards says NV-128 demonstrated safety in animal xenograft models without apparent toxicity.

Novogen said NV-128 was a novel flavonoid small molecule mammalian target of rapamycin or mTOR inhibitor, capable of inhibiting both mTORC1 and mTORC2 pathways which are central to the aberrant proliferative capacity of both mature cancer cells and cancer stem cells.

The company said the data demonstrated that NV-128 had much greater safety than some other mTOR inhibitors in mice bearing human ovarian cancer xenografts.

Novogen said most of the current compounds acting on this pathway are analogues of rapamycin, known as rapalogs.

The company said rapamycin and its analogues were regarded as the archetypal inhibitors of mammalian target of rapamycin.

In addition to their reported toxicities, rapalogs have been shown to contribute to the development of drug resistant tumors and ultimately reduced effectiveness over time due to their inability to efficiently inhibit mTORC2, a complex of mTOR with rapamycin-insensitive companion of mTOR.

Novogen said NV-128 administered daily resulted in a reduction in tumor volume of 51 percent relative to untreated control animals after 15 days, compared to a 50 percent reduction in mice given rapamycin every second day.

Whereas rapamycin treated mice lost eight percent of body weight over this period, NV-128 treated mice gained weight, finishing at six percent above their starting weight after the 15 day period, the company said.

Novogen said the weight gain was a significant indicator of lack of toxicity for NV-128, whereas the weight loss in the rapamycin treated mice reflected the well-documented toxicity of rapamycin in both animal and human studies.

After 21 days the tumors were removed and weighed.

In NV-128 treated mice, tumor mass was reduced by 41 per cent compared to vehicle controls, an effect equivalent to rapamycin treated animals in which tumor mass was reduced by 44 per cent.

Novogen said Marshall Edwards reported that NV-128 was judged to be without cardiac toxicity, further indicating the likely safety of NV-128 in clinical use.

In controlled studies undertaken by an independent contract laboratory, using guinea pigs attached to electrocardiograms, NV-128 was shown to have no impact on the interval between heart beats and was judged “to be devoid of cardiac toxicity”.

Novogen and Marshall Edwards research director Prof Alan Husband said the “combined findings of high level efficacy and good safety profile, including a lack of interference with heart functioning, is a significant step forward in the search for safe and effective cancer drugs that target mTOR”

Prof Husband said mTOR inhibitors had been given a high priority by pharmaceutical companies working in the oncology field, “but none have been able to produce clinical efficacy in the absence of toxicities”.

He said NV-128 had “great potential in human cancer management and we are moving as rapidly as possible to obtain approvals for human clinical trials to commence”.

Novogen said Marshall Edwards’ cancer biology group, headed by Dr David Brown, was exploring NV-128 for non-small cell lung cancer models.

Novogen was up 8.5 cents or 13.2 percent to 73 cents.

PSIVIDA

Psivida says 18-month results from its first human pharmacokinetic study of Iluvien shows efficacy increased with a high dose and decreased with a low dose.

Psivida said the trial was being conducted by Alimera Sciences, the licencee for Iluvien, am eye insert containing the corticosteroid, fluocinolone acetonide.

Psivida chief executive officer Dr Paul Ashton said the results in the 37-patient study showed a lower incidence of elevated [intraocular pressure] with Iluvien compared to the higher incidence shown in the data for studies of Retisert, a surgically inserted products containg the same corticosteroid developed by Psivida and approved by the US Food and Drug Administration.

Dr Ashton said the pharmacokinetic study showed "an increase in efficacy in the high dose group and a decrease in efficacy in the low dose group in the results at 18 months as compared to 12 months".

He said data from the 1000 patient phase III trial was due at the end of the year, which would "give a clearer picture of the relative efficacy of Iluvien dosages".

Psivida said the 36-month, open-label, phase II study was designed primarily to assess systemic exposure of fluocinolone acetonide after administration of Iluvien in patients with diabetic macular oedema.

The company said the pharmacokinetic study was designed to provide information on the safety and efficacy of Iluvien in a diabetic macular oedema patient population.

Of the 37 subjects enrolled, 20 were on the low dose of 0.23 micrograms per day and 17 patients were on the high dose of 0.45 micrograms per day.

The 18-month interim readout showed no adverse events related to intraocular pressure in low dose patients and a similar level of increased intraocular pressure in the high dose patients as reported at 12 months.

Psivida said that no patients receiving the low dose of Iluvien experienced intraocular pressure increases of 30 millimeters of mercury or greater at any time point, while 29 percent of the patients receiving the high dose of Iluvien experienced increases of 30mmHg or greater at some time point.

Psivida said a subset of 11 patients in the high dose group and 13 patients in the low dose group met the visual acuity inclusion criteria of the 1000-patient phase III trial.

Of the 11 patients in the high dose group, six patients had an improvement in best corrected visual acuity of 10 letters or greater from baseline and four patients of the high dose patients had an improvement of 15 letters or greater over baseline.

Of the 13 patients in the low dose group meeting the visual acuity criteria of the phase III trial, three patients had an improvement of 10 letters or greater from baseline, while no patients showed an improvement in BCVA of 15 letters or greater from baseline.

Psivida fell 57 percent to 10.3 percent to $4.95.

CYTOPIA

Cytopia says a US patent has been granted "providing protection for the claimed methods of selecting or designing a compound which interacts with JAK2".

Cytopia said JAK2 was a validated clinical target for cancer and the company held the exclusive licence to a family of patents for the drug targets JAK1 and JAK2.

Cytopia also said it had appointed Ashley Arnott as chief financial officer and company secretary with immediate effect replacing Gavan Flower.

The company said Mr Arnott held senior finance roles with private and public companies and is an experienced company secretary.

Cytopia was up half a cent or 4.35 percent to 12 cents.

LABTECH SYSTEMS

Labtech chief executive officer Lusia Guthrie says she is back on the road show following renewed interest from investors and brokers.

Ms Guthrie will speak at tomorrow's Financial Services Institute of Australasia (FINSIA) 'Profitable technology companies' lunch presentation along with Genetic Technologies chief executive officer Dr Paul MacLeman and Healthlinx managing director Nick Gatsios.

Ms Guthrie told Biotech Daily that during the financial crisis of the past year there was little interest in Labtech, despite sealing the deal with Biomérieux for the development and manufacturing establishment of the Previ Isola automated agar plate streaker.

Ms Guthrie said her company's technology had been installed in laboratories in France, Germany, Netherlands, Sweden, Italy, China and the US and was available in Australia.

Ms Guthrie said she was confident that Biomérieux would achieve strong sales, but it was a matter of waiting.

She said that it was unfortunate to "launch into the global recession" despite the automated plate streaker paying for itself within two years through staff cost savings along with ending the need to redo work and providing better streaking.

Ms Guthrie said the automated agar plate streaker sold for $US150,000 to $US200,000 ($A170,740 to $A227,618).

She agreed that investors were awaiting sales and royalties from Biomérieux but in the meantime Labtech was "planning the next move".

Ms Guthrie said there was another instrument on the way.

While she would say nothing specific about the technology Ms Guthrie confirmed that it was intended to provide a solution for a laboratory problem.

"We've identified a problem we want to solve and we want to solve it," Ms Guthrie said, adding that having "developed the concept and done some pilot work" the company's board would have to make the decision on whether to go ahead.

Ms Guthrie said detailed intellectual property strategies needed to be in place before anything further could be said or done on the project.

Labtech was up 1.5 cents or 11.1 percent to 15 cents.

USCOM

Uscom says its share plan closed on September 28, 2009 raising $1,134,342 through applications for 1,800,544 shares at 53 cents a share.

Uscom said the shares would be allotted and issued on October 2, 2009 and the company would have 41,800,544 shares on issue.

Uscom climbed 12 cents or 17.65 percent to 80 cents.

OBJ LTD

OBJ has requested a trading halt pending an announcement "of the results of a partner-funded study".

Trading will resume on October 2, 2009 or on an earlier announcement.

OBJ last traded at 0.4 cents.