Biotech Daily

Tuesday April 9, 2013

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: REVA UP 6%, ANTISENSE, USCOM DOWN 10%**

*** LSQ WELCOMES FEDERAL GOVERNMENT MCKEON REVIEW**

*** NOVOGEN ISOLATES MOST POTENT FORM OF CS-6**

*** BONE BN006 PHASE I RA TRIAL EQUALS ADALIMULAB AT HALF-DOSE**

*** VIRALYTICS: 'DOSE-RANGING PATIENTS TOLERATE IV CAVATAK'**

*** NANOSONICS TROPHON EPR INCREASES PROBE COVERAGE**

*** PRIMA PLAN PRICE CHANGE FROM 10c TO 95% OF 10-DAY VWAP**

*** PLATYPUS CAPITAL BELOW 5% IN SIRTEX**

*** PERPETUAL TAKES 8% OF SIRTEX**

MARKET REPORT

The Australian stock market climbed 1.45 percent on Tuesday April 9, 2013 with the S&P ASX 200 up 71.3 points to 4,976.8 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 16 fell, six traded unchanged and four were untraded.

Reva was the best, up three cents or 5.8 percent to 55 cents with 55,862 shares traded.

Avita, Nanosonics, Osprey and Phosphagenics climbed more than four percent; Alchemia, GI Dynamics and Neuren were up more than three percent; Cellmid and Living Cell rose more than two percent; Circadian and Starpharma were up more than one percent; with Acrux, Cochlear and Psivida up by less than one percent.

Both Antisense and Uscom led the falls, down 10.0 percent to 0.9 and 18 cents, respectively, with three million and 1,000 shares traded, respectively.

Viralytics lost 9.4 percent; Patrys and Prana fell four percent or more; Prima and Tissue Therapies were down more than three percent; Ellex, Genetic Technologies and Sirtex shed more than two percent; Bionomics, Clinuvel, Mesoblast, QRX and Resmed were down one percent or more; with CSL, Heartware and Universal Biosensors down by less than one percent.

FEDERAL GOVERNMENT, LIFE SCIENCES QUEENSLAND

Life Sciences Queensland has welcomed the release of the McKeon Review and the vision to embed health and medical research within the health system.

Life Sciences Queensland chief executive officer Mario Pennisi said he praised the findings and recommendations of the report and the opportunities that existed for the industry if the Federal Government takes on its recommendations.

“The Report’s plan to optimize current investment in health and medical research and in the long term manage and monitor 3-4 percent of the total Australian Government’s health expenditure on health and medical research is a farsighted and exciting proposal,” Mr Pennisi said.

Mr Pennisi said that by reshaping the sectoral leadership and the way health and medical research was funded in Australia would result in better tracking of investment and evaluation of outcomes.

“One area that would benefit immediately is clinical trials,” Mr Pennisi said. “The recommendations need to be considered and implemented, and that will require action and funding by the Government, and what better timing than in the lead up to a Federal Election,” Mr Pennisi said.

“We look forward to working with the government and our stakeholders to achieve the recommendations of the review,” Mr Pennisis said.

The McKeon Review - Strategic Review of Health and Medical Research – Better Health through Research Report was released by the Minister for Health, Tanya Plibersek yesterday and is available at http://www.mckeonreview.org.au.

NOVOGEN

Novogen says it has identified the ‘left-handed’ variant of lead cancer candidate CS-6 as 200-times more potent than the ‘right-handed’ version.

Novogen said that CS-6 was a chiral molecule, meaning it could exist in both left and right-hand forms known as enantiomers.

The company said that enantiomers often differed in biological activity, with one form being more active than the other, a difference the could lead to the weaker form inhibiting the more active form and where that happened, the enantiomers needed to be separated and used in isolation.

Novogen said that initial biological studies on CS-6 had used a mixture of the two enantiomers, a typical research strategy in early-stage drug development to save time and costs, with the purification and manufacture of the left and right-hand forms undertaken once a molecule demonstrated significant promise in pre-clinical studies.

The company said the two CS-6 enantiomers were screened in-vitro for activity against brain cancer (glioblastoma and meduloblastoma) cell lines and the data showed that one CS-6 enantiomer was about 200-times more active than the other against all cell lines.

Novogen chief scientific officer Dr Andrew Heaton said the ability to manufacture CS-6 in both left and right-hand forms was “a significant milestone in the development of this compound”.

“The indication that one form of CS-6 is active at nanomolar concentrations against a broad spectrum of brain cancer lines … indicates that the earlier potencies we have seen against cancer cells and cancer stem cells are likely to be even greater with the purified enantiomer,” Dr Heaton said.

Novogen chief executive officer Dr Graham Kelly confirmed to Biotech Daily that the left-handed variant showed the greater activity.

Novogen fell 2.5 cents or 10.2 percent to 22 cents with 1.1 million shares traded.

BONE MEDICAL

Bone says that interim phase I results show that BN006 has an anti-inflammatory effect on rheumatoid arthritis equivalent to that of adalimulab, at about half the dose.

Bone chief executive officer Peter Young told Biotech Daily that the eight-patient, phase I trial was a randomized, cross-over design, proof of concept experiment.

The company said that the objective of the concept study was to evaluate BN006's ability to reduce inflammation in the widely accepted collagen-antibody induced arthritis disease model and to compare its effect to adalimumab (Humira), one of the leading anti-tumor necrosis factor agents on the market for the treatment of rheumatoid arthritis.

Bone said that tumor necrosis factor (TNF) was one of the body's inflammatory agents that played an important role in the rheumatoid arthritis disease process, but was also important to a healthy immune response.

The company said that currently approved monoclonal antibody products like adalimumab worked by binding TNF, but could suppress the immune system and the study results showed BN006 had an anti-inflammatory effect equivalent to adalimulab, at about half the dose, weight-for-weight, despite causing about half the reduction in TNF level.

The company said that BN006 "may have a more selective mechanism of action and fewer immunosuppressive side effects" compared to marketed anti-TNF products.

Bone said that BN006, derived from its Mozaic peptide discovery technology, was easily measured in the bloodstream and had a long half-life.

Bone's chair and chief scientific officer Dr Roger New said that the next efforts would be to further elucidate BN006's anti-inflammatory mechanism of action, determine whether it could be administered by mouth and determine the low end of its dose response.

Bone also said that the QP12C16 single-dose Capthymone study would further evaluate the pharmacokinetic profile of the oral parathyroid hormone product, in comparison to Forteo (teriparatide or the 1-34 peptide fragment of parathyroid hormone), an injectable parathyroid hormone product approved for the treatment of osteoporosis, to aid in the ongoing selection and optimization process of the product formulation and the most appropriate development path.

The company said that a previous human trial using a broad-specificity radio-immune assay showed that two alternative oral formulations of Capthymone using its Axcess III and IV oral peptide technologies achieved parathyroid hormone levels similar to Forteo levels and demonstrated biological activity measured as increases in blood calcium.

Bone said that using a specific Enzyme-linked immuno sorbent assay (Elisa) to measure 1-34 fragment levels in the blood, it was clear from the study results so far that Capthymone, absorbed from the intestine and passing through the liver before reaching the systemic circulation, produced a different pharmacokinetic fragment profile from Forteo, administered by subcutaneous injection and not further metabolized before entering the bloodstream.

The company said that the most likely explanation of the findings was that the dose delivered by Capthymone was metabolized by the liver, resulting in blood levels of parathyroid hormone fragments that could be measured by radio-immune assay but not intact 1-34 parathyroid hormone measured by Elisa.

Dr New said that while there was some suggestion of a dose difference in the effect on calcium between the two Capthymone doses, neither dose had an effect on this biological marker significantly different from Forteo in the single-administration study.

The company said it would investigate and confirm this interpretation in follow-on experiments.

Bone was up 0.1 cents or 100 percent to 0.2 cents with 700,000 shares traded.

VIRALYTICS

Viralytics says patients have tolerated a dose escalation phase I trial of intravenous Cavatak for late stage melanoma, prostate, breast or colorectal cancer.

Viralytics said that Cavatak (Coxsackievirus type A21) was well tolerated with some evidence of stable disease despite most patients only receiving a single dose.

The company said that nine patients received a single intravenous infusion ranging from a dose of 106 to 1010 infectious units and one patient received two infusions of Cavatak and of the 10 patients enrolled, eight were evaluable for assessment.

Viralytics said Cavatak was well tolerated for intravenous administration with no treatment-related serious adverse events and no subjects withdrawn due to adverse events.

The company said that some patients displayed transient or stable reductions in lesion size and/or stable disease despite most receiving only a single dose of oncolytic virus.

Viralytics said that no objective responses were observed, but two subjects displayed stable disease at Day 84.

The study investigator New South Wales St George Hospital cancer care unit's Prof Winston Liauw said the study "met the key endpoint of patient tolerability".

"Single-dose intravenous administration Cavatak was well tolerated, demonstrated secondary replication, presence inside some cancer tissue and provided evidence for some stable disease," Prof Liauw said.

"Overall, the study observations provide strong foundations for phase II investigations employing a multi-dose administration schedule to study the efficacy and safety of Cavatak in patients with late stage solid cancers," Prof Liauw said.

Viralytics said it had also finalized in-vitro laboratory studies demonstrating the oncolytic activity of Cavatak in human lung cancer cell lines when used in conjunction with docetaxel.

The company said that lung cancer cells were grown in culture and then treated with either a combination of Cavatak and docetaxel, Cavatak alone or docetaxel alone.

Viralytics said that the combination of Cavatak and docetaxel provided a moderately to strongly synergistic effect compared to the use of either product alone.

The company said that further in-vitro experiments confirmed that docetaxel had no negative effect on the rate of Cavatak replication in human lung cancer cell lines and, overall, the results provided evidence that Cavatak and docetaxel had the potential to be successfully used in combination therapy regimens.

Viralytics said it was planning a combination trial of Cavatak with docetaxel or paclitaxel or carboplatin as part of the phase I/II multi-dose intravenous Cavatak trial for resistant malignancies to be conducted in the UK.

The company said the first stage would administer Cavatak as a monotherapy in late stage melanoma, non-small cell lung, metastatic bladder and castrate-resistant prostate cancer patients and in the second stage Cavatak would be administered in conjunction with docetaxel or carboplatin or paclitaxel to the cancer type identified as the most promising target from the initial stage.

Viralytics said it hoped to begin the study by January 2014.

Viralytics chief executive officer Dr Malcolm McColl said the results of the phase I trial showed Cavatak was "well-tolerated in patients and our laboratory studies demonstrate that there may be compelling potential benefits from the combination of Cavatak and docetaxel".

The company said it was well-placed to begin phase I/II intravenous studies in patients with common tumor types such as prostate, lung, melanoma and bladder cancer and a positive outcome in these studies would broaden Cavatak's potential application.

Viralytics fell three cents or 9.4 percent to 29 cents.

NANOSONICS

Nanosonics says it has expanded the market reach of its Trophon EPR ultrasound probe disinfection system, with a significant increase in the number of certified probes.
Nanosonics said it had accelerated its probe testing and certification program adding 219 probes from manufacturers Esaote, Hitachi-Aloka, Ultrasonix and Zonare, in addition to the extensive list of approved probes from GE, Philips, Siemens, Sonosite, Toshiba, BK Medical, and Prosonic to a total of 458 approved probes.
Nanosonics chief executive officer Dr Ron Weinberger told Biotech Daily that the company had approvals for more than 90 percent of commonly used probes with approvals including ultrasound probes for surgery, paediatric and neo-natal use as well as surface scans.
In a media release Dr Weinberger said the company had “strong engineering and commercial relationships with most of the ultrasound manufacturers at senior executive levels”.
The company said that ultrasound practitioners required probe manufacturer’s approval before they would deploy a new disinfection system such as Trophon EPR as unapproved use could void manufacturers’ warranties, which could be costly to users.
“As more customers move away from manual disinfection methods, compatibility with Trophon EPR is becoming an increasingly important purchasing consideration for ultrasound system buyers,” Dr Weinberger said.
“Also, proving chemical and process compatibility between the Trophon EPR and the ultrasound system is a key sales enabler,” Dr Weinberger said.
“Probe manufacturers are now indicating that they need approval for use with the Trophon EPR or they will lose sales.” Dr Weinberger said.
Nanosonics said that the Trophon EPR was emerging as the new standard-of-care for ultrasound probe disinfection.
The company said that some manufacturers were working with it to design new probes with features that specifically complemented the Trophon EPR and ensure compliance with US Food and Drug Administration regulations.
Nanosonics was up two cents or 4.4 percent to 47 cents.

PRIMA BIOMED

Prima has changed its share plan to raise $15 million from 10 cents a share to 95 percent of the 10-day volume weighted average price to the expected issue date, May 17, 2013.
Prima said the change of price was the result of “potential market conditions and feedback from … shareholders”.
Prima said that all other conditions remained the same as previously announced with the share plan record date of March 28, 2013 (BD: Apr 2, 2013).
Prima fell 0.3 cents or 3.2 percent to 9.2 cents with 1.3 million shares traded.

SIRTEX MEDICAL

Platypus Asset Management reduced its substantial shareholding in Sirtex from 3,897,856 shares (6.99%) to 2,208,955 shares (3.96%).
The substantial shareholder notice said that since its last notice in 2011, the Sydney-based Platypus sold 1,688,901 shares for $16,568,052 or an average price of $9.81 a share (BD: Sep 8, 2011).
Sirtex fell 25 cents or 2.4 percent to $10.36.

SIRTEX MEDICAL

Perpetual and its subsidiaries have increased their substantial shareholding in Sirtex from 3,045,755 shares (5.46%) to 4,376,914 shares (7.85%).
Perpetual said that the 1,331,159 shares were bought between December 27, 2012 and April 5, 2013 at prices ranging from $9.80 to $13.30.