Biotech Daily

Monday April 20, 2009

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP; ALCHEMIA UP 14%, OPTISCAN DOWN 10%**

*** BIOGUIDE BRIEF: BLESSING POLARTECHNICS-FERMISCAN'S MARRIAGE**

*** POLARTECHNICS, FERMISCAN CORRECTION**

*** QRX PHARMA'S MOXDUO 'FEWER SIDE EFFECTS THAN COMPONENTS'**

*** ENTRUSTING METABOLIC'S NEW BOARD WITH POLYNOVO**

*** VIRALYTICS INCREASES PHASE I CAVATAK CANCER DOSE**

*** ATCOR WINS $US579k CONTRACT**

*** NOVOGEN'S NV-128 STOPS CANCER CELL DIFFERENTIATION**

*** PROGEN'S EPIGENETIC TECHNOLOGY 'INHIBITS TUMOR GROWTH'**

MARKET REPORT

The Australian stock market retreated 0.2 percent on Monday April 20, 2009 with the S&P ASX 200 down 7.7 points to 3,769.0 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 13 fell, seven traded unchanged and six were untraded.

Alchemia was best, up five cents or 13.9 percent to 41 cents with 558,920 shares traded followed by Bionomics up 12.5 percent to 22.5 cents, Starpharma up 11.9 percent to 33 cents, Biota up 10.8 percent to 72 cents and Antisense up 10 percent to 3.3 cents.

Clinuvel climbed 5.5 percent; Benitec, Genera and Novogen were up more than three percent; Viralytics rose 2.6 percent; with Impedimed, Resmed and Sirtex up more than one percent. Outside the Top 40, Neuren rose 48.1 percent to four cents with 33.2 million shares traded.

Optiscan led the falls, down 0.5 cents or 10 percent to 4.5 cents with 1,055 shares traded.

Avexa and Labtech lost nine percent or more; Polartechnics fell 7.7 percent; Living Cell was down 6.9 percent; Phosphagenics and Progen both fell 5.56 percent; Prana fell 4.9 percent; Nanosonics, Pharmaxis and Tissue Therapies shed more than two percent; with Chemgenex and CSL down more than one percent.

MARC SINATRA'S BIOGUIDE BRIEF: POLARTECHNICS, FERMISCAN

On the face of it, the Polartechnics friendly takeover of Fermiscan makes sense. Both companies operate in the area of cancer screening, with Polartechnics focused on cervical cancer and Fermiscan focused on breast cancer.

Although the technologies are different, the common thread of cancer screening should create reasonable synergies from clinical trials and beyond, even though the specifics won't be identical.

Polartechnics' Chinese and Indian ties may also prove a bonus for Fermiscan given the difficulty to gain regulatory approval for cancer screening tests in Western markets. The deal also seems fair to both groups of shareholders, with Fermiscan holders receiving three Polartechnics shares for every two Fermiscan shares they hold.

This represents an 8.3 percent premium to Fermiscan's close of 18 cents on April 17, 2009 and is justified by the $7.4 million dollars Fermiscan has in the bank at a time when cash truly is king.

Polartechnics had only $870,000 in the bank as of their December 30, 2008 accounts, compared to a cash burn of $4.4 million for the year.

As for the future of the merged entity, both companies have issues. Polartechnics forecast impressive revenues of $6.8 million in 2009, $67 million in 2010 and $151 million in 2011 at its AGM last year. But, these numbers are curious when you consider that in 2008 sales revenue was $779,000 compared to cost of goods sold of $803,000.

Where Polartechnics hopes to make money is on the consumables used in running their Truscreen device and in Western countries this is a tried and true formula.

In China and India, where the ability to pay is much lower and where anything that can be copied will be copied, a significant degree of risk is added.

The problem with Fermiscan's breast cancer test is that only Fermiscan and the academic from whom they acquired the technology Prof Veronica James have been able to produce reasonable results. Independent researchers have tried and failed to do so.

For the test to be taken seriously, the company needs to produce results from an appropriately designed prospective clinical study in a breast cancer screening program demonstrating a yield of breast cancers at least similar to that obtained under the current standard screening regimen.

Despite these issues, the merger appears to be in the best interests of both Polartechnics and Fermiscan shareholders.

Polartechnics fell one cent or 7.7 percent to 12 cents.
Fermiscan climbed one cent or 5.6 percent to 19 cents.

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POLARTECHNICS, FERMISCAN

Friday's report on the merger suffered a précis malfunction and should have read "Polartechnics and Fermiscan will merge to create what they describe as 'Australia's largest women's health business'."

Biotech Daily apologizes for any embarrassment caused by the sub-editor's error, who claimed the announcement was made at 4.37pm after the market closed on a Friday and the edition had been 'put to bed'. The sub-editor is on leave at Guantanamo Bay.

QRX PHARMA

QRX Pharma says a phase III pilot study shows that Moxduo reduces pain more than its morphine and oxycodone component doses with fewer and less intense side effects.

QRX said Moxduo was compared to equi-analgesic doses of morphine and oxycodone.

QRX chief financial officer Chris Campbell said the trial had six arms with oral 12mg/8mg Moxduo immediate release (IR) and 6mg/4mg Moxduo IR compared to 12mg morphine; 8mg oxycodone; 6mg morphine; and 4mg oxycodone.

In a media release the company said the 12mg/8mg Moxduo IR was the preferred dose for optimal efficacy and tolerability as well as providing sample size guidance for the phase III combination rule study for a new drug application submission in 2010.

QRX Pharma chief executive officer Dr John Holaday said that having achieved statistical significance in measures of decreased pain intensity with Moxduo immediate release (IR) compared to its component doses, "this pilot study exceeded expectations".

"Completed ahead of schedule and on budget, trial data clearly demonstrated the clinical and commercial value of our patented dual-opioid, with the potential to give patients greater tolerability than morphine or oxycodone alone," Dr Holaday said.

"From these data, we are confident that our upcoming phase III combination rule study will prove successful," Dr Holaday said.

The company said the randomized, double-blind study of 197 patients at six US clinical research sites, compared Moxduo IR to morphine and oxycodone in managing acute pain during the first 24 hours following a scheduled surgical procedure of bunionectomy.

When postoperative pain reached four on a scale of zero to 10 with 10 the most severe, patients received Moxduo IR, morphine or oxycodone every six hours for 48 hours.

The primary endpoint was changes in the pain intensity scores and secondary endpoints included pain relief and global assessment of effect and safety.

QRX said that in terms of reduced pain intensity scores and other related measures, the analgesic effects of 12mg/8mg Moxduo IR were 80-100 percent greater than the components, morphine or oxycodone. The 6mg/4mg Moxduo IR dose also showed similar improvements when compared to its individual components.

QRX said that "significantly, the frequency of moderate to severe adverse events including nausea, vomiting, constipation and dizziness was 25 percent to 75 percent lower among patients on Moxduo IR compared to those receiving equi-analgesic doses of morphine or oxycodone alone".

QRX said patients receiving morphine or oxycodone alone were two to four times more likely to prematurely discontinue dosing than those on Moxduo IR.

"The improved tolerability profile should enable pain practitioners to prescribe higher doses of Moxduo IR to achieve better pain relief with fewer side effects than morphine or oxycodone alone," Dr Holaday said

QRX said additional studies evaluating Moxduo IR versus Percocet in patients with joint replacement surgery are underway, with results expected by September 2009.

QRX was up three cents or 6.7 percent to 48 cents.

METABOLIC, POLYNOVO, ENTRUST

Entrust Funds Management expects Metabolic's new board to complete a review of the company and its 60 percent holding of Polynovo within three months.
Entrust Funds Management acquired 19.8 percent of Metabolic through Adelaide plastic surgeon Dr Tony Moore (BD: April 3, 2009) who acquired 45,492,701 shares (15.09%) from director Franklyn Brazil and Brazil Farming, becoming a substantial shareholder with a total of 59,713,219 shares (19.8%).
Mr Brazil's holding was believed to be among the shares used to prevent the December acquisition of Polynovo from Xceed Capital and Commonwealth Scientific and Industrial Research Organisation (BD: Nov 27, Dec 18, 2008), later approving the 60 percent controlling acquisition of Polynovo, whose chief executive officer Dr Ian Griffiths resigned unexpectedly in February (BD: Feb 6, 2009).
The managing director of Entrust Funds Management David Franklyn has been appointed chairman of Metabolic and told Biotech Daily the Metabolic board would meet this week and he hoped to have a business plan ready within three months.
Mr Franklyn said one question related to Polynovo's Novosorb technology which had "so many applications" the directors would need to consider how best to apply the technology.
The Metabolic announcement said directors Paul Lappin and Iain Kirkwood had resigned, effective immediately, and Mr Kirkwood had also resigned as company secretary.
Metabolic's board comprises Mr Franklyn, Entrust's Oliver Stevens, former Xceed chief executive officer David Kenley and Xceed director George Cameron-Dow. Director Don Clarke remains and Christopher Mews has been appointed company secretary.
Mr Franklyn said the combined Metabolic and Polynovo entity had $14 million at December 31, 2008. Separately, Mr Franklyn said Entrust expected its 3.5 million Progen shares to be accepted into the proposed $1.10 buy back.
Metabolic fell 0.3 cents or 10.3 percent to 2.6 cents.

VIRALYTICS

Viralytics has received ethics committee approval to increase the dosage levels of Cavatak in its phase I intravenous breast cancer, prostate cancer and melanoma trial.
Viralytics said dosing would commence at what was the highest dosing level of the original trial schedule and escalate to approximately 100-fold higher than originally planned.
The company said the intravenous trial would comprise nine patients and a further six patients needed to be recruited.
Viralytics said that while phase I studies were primarily designed to assess patient tolerance, increasing the Cavatak dosing schedule might provide meaningful preliminary efficacy data in preparation for a phase II study. Overall, Cavatak was well-tolerated by late stage cancer patients participating in all three Viralytics phase I clinical trials.
Viralytics fell 0.1 cents or 2.63 percent to 3.9 cents.

ATCOR MEDICAL

Atcor says it has won a US$579,000 ($A808,000) contract from "a leading international pharmaceutical company" for its Sphygmocor systems and clinical trial support services.
Atcor said Sphygmocor measured central blood pressures and arterial stiffness noninvasively and the contract was to an existing client.
The company said the contract brought the total value of US pharmaceutical trial contracts secured over the past 11 months to $US7.9 million.
Atcor fell half a cent or 2.1 percent to 23.5 cents.

NOVOGEN

Novogen says NV-128, a not only induces cell death in ovarian cancer stem cells, but also blocks their differentiation into structures required for tumor growth.

Novogen said a poster presentation at the American Association for Cancer Research in Denver by Yale University School of Medicine's Dr Ayesha Alvero showed that in addition to an inhibitory effect on ovarian cancer stem cell growth, the synthetic isoflavonoid compound, NV-128, displayed "a remarkable ability to inhibit differentiation of [ovarian cancer stem cells] into formation of new blood vessels".

The company said the anti-proliferative effects were demonstrated to be achieved as a result of NV-128 inhibiting phosphorylation of the pro-survival mTOR pathway resulting in mitochondrial depolarization and cell death.

Previously, Novogen's group director of research Prof Alan Husband told Biotech Daily that mTOR stood for 'mammalian target of rapamycin' (BD: Mar 20, 2009).

Today, Novogen said time-lapsed photographic morphometry showed how NV-128 induced morphological changes in ovarian cancer stem cells after 24 hours, even when dosed as low as 1µg/ml with a progressive clearing of cytoplasm and condensation of nuclear material.

Novogen said the effect of NV-128 on ovarian cancer stem cell vessel formation was observed by plating ovarian cancer stem cells in high-density matri-gel either without NV-128 as controls or in the presence of 0.1 mg/ml NV-128 and observing for 48 hours.

Whereas the control cultures showed differentiation of the stem cells into endothelial-type cells forming structurally intact blood vessels in the culture plates, cells cultured in the presence of NV-128 showed no differentiation and no structural elements were observed.

Ovarian cancer stem cells represent a highly chemo-resistant cell population, allowing them to survive conventional chemotherapy, Novogen said. So these cells were considered to be the potential source of tumor induction and post-treatment recurrence.

The Yale team, headed by Prof Gil Mor, recently reported the identification and characterization of ovarian cancer stem cells using the CD44 marker and demonstrated pronounced up-regulation of the mTOR survival pathway in these cells.

Novogen said the team previously reported that NV-128 was able to specifically induce mTOR dephosphorylation resulting in inhibition of both mTORC1 and mTORC2 activity in mature ovarian cancer cells derived from established human cancers and cultured in vitro.

In mice with human ovarian cancers established by grafting techniques NV-128 caused substantial cancer cell death, reducing tumor growth with no apparent toxic side-effects.

Prof Mor said his team had demonstrated that "by inhibiting the mTOR pathway in both the cancer stem cells and the mature cancer cells, we are able to inhibit development of structural elements necessary for tumor development as well as limit the number of cancer cells".

"These results open a new avenue for the development of better treatment modalities for ovarian cancer patients," Prof Mor said.

"We are encouraged by these data from animal studies showing a combination of anti-cancer activities of NV-128, coupled with an apparently high safety profile," Prof Husband said.

"This anti-angiogenic effect, coupled with the absolute effects on cell survival, demonstrate the potential for NV-128 to become a powerful new tool in prevention as well as treatment of cancer," Prof Husband said.

Novogen said it was in advanced negotiations to licence NV-128 to its 72 percent-owned subsidiary Marshall Edwards for its clinical development as a potential cancer therapeutic.

Novogen was up 1.5 cents or 3.4 percent to 45.5 cents.

PROGEN

Progen says its epigenetic technology “successfully inhibits tumor growth”.
Progen said the results of the pre-clinical experiments, presented by Progen’s collaborators at the American Association for Cancer Research conference showed that Progen’s product was effective in switching on anti-cancer genes, which the company said was “a significant achievement in epigenetics research and cancer therapeutics”.
Progen chief executive officer Justus Homburg said the findings “reinforced Progen’s position at the forefront of anti-cancer drug research”.
“Epigenetics represents an exciting new target for cancer therapeutics and is a focus of this AACR meeting,” Mr Homburg said.
“We are very proud to have achieved such promising results in this exciting area of research,” he said.
Progen said epigenetics technology was “one of the latest breakthroughs in cancer drug development” which focused on expression (switching on) or silencing (switching off) of certain genes.
Progen said that with its collaborators research focused on lysine specific demethylase 1 enzyme, which contributed to the silencing of important tumor suppressor genes.
They have developed PG11144 that inhibits lysine specific demethylase 1 and reactivated or expressed the silenced genes that were inactivated in cancer.
Progen’s chief scientific officer Dr Laurence Marton said the results showed the product inhibited tumor growth in test tubes and living organisms.
Dr Marton said the use of lysine specific demethylase 1 inhibitors was “a highly promising and novel approach to cancer prevention and therapy, and may be suitable for multiple indications”.
In addition to its epigenetics findings, Progen also presented an update on its cell proliferation technology at the AACR Conference.
Progen said its lead cell proliferation product, PG11047, targeted hyper-proliferating cells specifically to inhibit tumor growth and was in two phase I clinical trials.
The pre-clinical research presented at the conference showed the product provided a significant additive anti-cancer effect when combined with Cisplatin and Avastin when compared with either drug alone in lung cancer and prostate cancer models respectively.
Progen said it was progressing PG11047 through early clinical development in parallel to additional translational studies to determine the most promising indications.
Mr Homburg said to date, 44 patients had been treated in the monotherapy PG11047 phase I trial, and more than 130 patients in combination studies with approved anti-cancer therapies.
Progen said the dosing regime in the monotherapy trial had been escalated “far beyond Progen’s original expectations”.
“While we expect to find the maximum dose soon, we already have supporting data that the drug will have a large therapeutic window when given as a monotherapy,” Mr Homburg said.
Mr Homburg said the findings in Progen’s epigenetics and cell proliferation technologies represented another important milestone in the development of its anti-cancer portfolio.
“These latest findings prove we have the technology, the expertise and the resources to progress our strong product pipeline,” he said.
Progen fell five cents or 5.6 percent to 85 cents.