Biotech Daily

Tuesday February 10, 2009

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: BIONOMICS UP 17%, AVEXA DOWN 13%**

*** GBS' DR JOSHUA FUNDER DETAILS FUNDING TO BIO-BREAKFAST**

*** VENTRACOR CABLE FAILURE - THREE DEAD; SHARES SUSPENDED**

*** HEARTWARE IMPLANTS 10th HEART PUMP PATIENT**

*** COCHLEAR: RECORD H1 PROFIT UP 22% TO $70m; RECORD REVENUE**

*** VIRALYTICS BEGINS HEAD, NECK CANCER PHASE I TRIAL**

*** STARPHARMA: COMPETITOR RESULTS GOOD NEWS FOR VIVAGEL**

*** DR PETER JENKINS DEPARTS IMMURON**

MARKET REPORT

The Australian stock market fell 0.6 percent on Tuesday February 10, 2009 with the S&P ASX 200 down 19.95 points to 3,488.7 points.

Nine of the Biotech Daily Top 40 stocks were up, 11 fell, seven traded unchanged and 13 were untraded.

Bionomics was best, up three cents or 16.67 percent to 21 cents with 5,000 shares traded, followed by Living Cell up 0.8 cents or 8.89 percent to 9.8 cents and Polartechnics up one cent or 7.41 percent to 14.5 cents.

Acrux, Circadian and Cochlear climbed more than four percent; Cellestis was up 3.9 percent; Mesoblast and Pharmaxis were up more than one percent; with Arana up 0.62 percent.

Avexa led the falls, down one cent or 12.82 percent to 6.8 cents with 358,614 shares traded, followed by Impedimed down 11.56 percent to 65 cents and Universal Biosensors down five cents or 9.09 percent to 50 cents.

Genetic Technologies lost 7.89 percent; Resmed fell 4.13 percent; Alchemia and Sirtex were down more than three percent; Benitec and Clinuvel shed more than two percent; with Biota, CSL, Heartware and Novogen down more than one percent.

BIO-MELBOURNE NETWORK

GBS Venture Partners' Dr Joshua Funder says Australian venture capital is still viable and one of the first places to look for funds is among existing investors.

Addressing a Bio-Melbourne Network Bio-Breakfast on 'Funding opportunities in a capital constrained market' Dr Funder said the year ahead was likely to be tough for the sector with fewer funds being sought by more companies.

He said companies should first look to their own investors and think flexibly about funding options. Dr Funder said that it was important to raise funds for two and three years ahead, to avoid coming back to the market and acknowledged that the longer it took to raise the funds the worse the problems became for the companies in question.

He said funds were still available through Australian and foreign venture capital firms, but there would be attrition in venture capital funding.

"The availability hasn't changed a lot for private companies, but there are more companies looking for it," Dr Funder said. "Australian venture capital is still viable."

He said corporate venture capital was an important source of funds providing both financial and scientific capital for companies and that Australia's reputation in science and technology helped attract corporate venture capital.

He said partnerships were important and gave as an example the $US75 million upfront Forest Laboratories payment to Phenomix on a phase III diabetes trial.

Dr Funder said private investment in public enterprise (Pipes) were a further form of funding and gave as examples the GBS and Alta Partners investment in Chemgenex which brought about a transformation of the company.

Dr Funder said Peplin benefitted from a similar investment.

He noted Pipes investments had "pros and cons" especially relating to both the valuation and liquidity of the target company.

"Pipes have to be carefully thought through, but they are a live and creative source of funds," Dr Funder said.

He said that a suite of Australian companies had revenue streams including Sirtex, Cogstate, Biota and Pharmaxis.

Dr Funder said that to attract funds from beyond the life sciences sector, investors would want to see success.

"As we see more late stage companies earning revenue, it will attract capital from outside our own sector," he said.

"Grants continue to be available, nationally and internationally." He said grants were available from governments as well as private sources like the Bill Gates Foundation.

He said he was not sure where angel and seed investors would go in this market, but said "It's a great opportunity to invest. What is no longer viable for the next 12-24 months is IPOs.

"Consolidation of companies without cash reserves or additional funding is not an answer, it is not an active live source," he said.

Dr Funder said that belt-tightening was important and that Alchemia cut heavily and early but it may look modest as the year progresses. He said it was important to keep programs, intellectual property and people "but don't run out of money".

"Demand for health care is less impacted by the economic crisis. Health care is not discretionary. The pharmaceutical industry has a lot of cash, it hasn't been quick on M&A but they have begun partnerships," Dr Funder said.

He said the Commercial Ready Grant scheme was "a terrific matching program" and some form of commercial ready should be reintroduced as well as a clinical ready program.

He said that Australia had the fourth largest superannuation system in the world, but very little was spent on biotechnology.

VENTRACOR

Ventracor has issued a “voluntary Urgent Field Safety Notice” for its LVA4 Ventrassist left ventricular assist device, catalogue number VA166.
Ventracor said there had been 11 reported cases of “lead integrity problems” with “a number of confirmed cases of conductor fracture within the percutaneous [through the skin] lead, between the implantable blood pump and the intermediate connector”.
Chief executive officer Peter Crosby told Biotech Daily the problems were outside the body, not internal and a recall in 2005 was a different problem which had been fixed.
The company said statistical analysis “completed very recently” showed that the field reliability of the VA166 did not meet Ventracor’s targets.
Ventracor said lead integrity problems had been reported in 11 patients, of whom there have been three deaths and the remainder have had repairs performed, a pump exchange, or a heart transplant.
The company said there were three patients who had traumatic accidental lead damage, and eight other patients with conductor fracture.
In some cases, failure to follow the instructions for use was a contributing factor.
Ventracor said 188 patients had been implanted with the LVA4-VA166 heart pump and 123 patients were ongoing.
The company has advised physicians that no new patients should be implanted with the VA166 and said it was working with its physician advisors to develop guidelines for management of patients already implanted with the device.
Ventracor said the Field Safety Notice did not affect other products such as the Model LVA3 Ventrassist left ventricular assist device (LVAD) catalogue number VA016, which has been implanted in over 220 patients worldwide and was still available for sale.
The company said the impact of the Field Safety Notice on several issues was unknown but it expected to make an announcement in the week beginning February 23, 2009.
The issues include remedial action required for the VA166 to be reintroduced to the market; the impact on revenue and Ventracor’s financial position, including the expected take-up of the Ventrassist LVA3 as an alternative device; and the intentions of one party with whom the company was in discussions regarding a potential sale and another party that was understood to be considering a debt financing proposal.
Ventracor requested the ASX extend its trading halt (BD: Feb 6, 2009) to a suspension.
Ventracor last traded at 8.3 cents.

HEARTWARE

Heartware says Northwestern Memorial Hospital has become the third center to implant its ventricular assist system in its US clinical trial conducting two implants last week.
The implants were performed by the surgical director of the Advanced Heart Failure Program of the Bluhm Cardiovascular Institute, Dr Edwin McGee.
Dr McGee is a cardiothoracic surgeon with special interest in heart failure, transplantation, mechanical assistance, coronary surgery, valve repair and aortic surgery.
“After our first implants of the Heartware System, it’s clear to us why this device is generating such enthusiasm among the clinical community,” Dr McGee said.
“The small size of the pump allows for a relatively quick and straightforward implantation,” Dr McGee said. “The elimination of the abdominal pump pocket typically required to implant larger devices should translate into important clinical benefits,” he said.
Heartware said 10 patients had been enrolled to date in its bridge-to-transplant trial.
The trial will enroll up to 150 patients at a maximum of 28 centers.
Heartware fell one cent or 1.52 percent to 65 cents.

COCHLEAR

Cochlear's net profit after tax for the six months to December 31, 2008 was up 22 percent to $69,936,000 on revenue up 19 percent to $355,227,000.
Cochlear said the revenue and profit figures were both half year records for the company.
The revenue came primarily from sales of Cochlear's hearing implant units, with sales up two percent to 9,178 units with a global market share of 70 percent and sales revenue up 22 percent to $301.1 million for the half year.
Sales revenue for the bone anchored hearing implants was up 25 percent to $45.8 million.
Cochlear said core basic earnings per share was up 19 percent to $1.334 and a dividend of 80.0 cents will be paid.
Cochlear's chief executive officer Dr Chris Roberts said the global financial crisis did not appear to have an impact in Cochlear's business model, but there had been a downturn in sales to China.
Cochlear climbed $2.30 or 4.36 percent to $55.00.

VIRALYTICS

Viralytics' phase I head and neck cancer trial has begun with the injection of Cavatak (Coxsackievirus A21) into the first patient.
Viralytics said ethics approval for its fourth clinical trial was announced in December (BD: Dec 9, 2008), site initiation was completed in mid-January 2009 and successful screening of the first patient was completed late January 2009.
The company said that data from this trial, together with results from existing clinical evaluations of Cavatak in patients with late stage melanoma, breast and prostate cancer (solid tumors) will expand the product profile of tolerance, bio-availability and anti-cancer mode of action in solid tumors.
Viralytics said the primary objective of the study was to determine the safety and efficacy of Cavatak given by intra-tumoral injection.
Secondary objectives include the evaluation of Cavatak replication, immune response to Cavatak and any evidence of anti-tumor activity.
The study is a nine-patient dose escalation trial comprising three groups of patients.
The first group will receive one injection, the second group three injections and the third group six injections of Cavatak.
The trial is being conducted at the Calvary Mater Hospital in Newcastle, New South Wales with principal investigators Prof Stephen Ackland and Dr Girish Mallesara.
Trial details are at: http://clinicaltrials.gov/ct2/show/NCT00832559?term=viralytics&rank=3
Prof Ackland said there were "limited effective treatments for cancers of the head and neck that either re-grow or are too advanced to be managed by surgery and/or radiation".
"We are very interested as to whether injection with Cavatak will show an effect on such cancers," Prof Ackland said.
"In addition, data generated in this study will allow a greater understanding of the mechanism of action of Cavatak and the nature of the immune response of the patient," he said.
Viralytics said cancers of the head and neck, which include cancers of the buccal cavity, head and neck subset, larynx, pharynx, thyroid, salivary glands and nose/nasal passages, account for about six percent of all malignancies in the US.
The company said 45,000 cases of head and neck cancer were diagnosed each year.
If caught early, the prognosis is excellent. However, about half of all cases of head and neck cancer are not identified until the disease is at an advanced stage.
Viralytics was unchanged at four cents.

STARPHARMA

Starpharma says Pro2000 gel, a candidate microbicide similar to Starpharma's Vivagel, has demonstrated partial effectiveness in preventing HIV infection in women.
Starpharma said the study found that 99 percent of women in the trial reported that they would use a topical microbicide gel that was approved for HIV prevention.
Starpharma chief executive officer Dr Jackie Fairley told Biotech Daily that the US-based Indevus Pro2000 trial was "the first time a topical microbicide had shown efficacy in a human HIV trial".
Starpharma said in a media release to the ASX that the results were "encouraging news for women seeking options to protect themselves against HIV infection".
With the lack of any demonstration of efficacy with human trials of HIV vaccines, this result provides a real boost to the opportunity for topical microbicides such as Vivagel.
Vivagel has demonstrated safety in humans and efficacy in animals.
Starpharma said that although the result from the completed clinical study was not statistically significant and was insufficient to enable registration, it was an important milestone for the product category.
Starpharma said Pro2000 gel was also shown to have a good safety profile, no different from the placebo.
Starpharma said the findings were significant, given that the active ingredient in Pro2000 gel was "in many respects similar to that of Vivagel".
"Given the similarity of the two products, this is excellent news for Starpharma," Dr Fairley said in the Starpharma release.
"Importantly, Vivagel has a number of differentiating factors including its activity in HIV, HSV-2 (genital herpes) and all clinically relevant strains of human papillomavirus and its lack of absorption into the bloodstream," Dr Fairley said.
The completed study also showed that another candidate microbicide, Buffergel, which relies on a fundamentally different mechanism of action, was not effective in reducing the risk of HIV infection.
Dr Fairley said Buffergel was owned by Johns Hopkins University spin-out Reprotect inc
Starpharma said Vivagel was being developed under two investigational new drug applications to the US Food and Drug Administration for the prevention of HIV and genital herpes and was in phase IIa human trials.
Starpharma was untraded at 20 cents.

IMMURON

Immuron (formerly Anadis) says Dr Peter Jenkins has retired as a director.
Dr Jenkins joined the company in 1994.
Immuron was untraded at 4.1 cents.