Biotech Daily

Tuesday February 9, 2010

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: AVEXA UP 18%; CHEMGENEX DOWN 20%**

*** COMMERCIALISATION AUSTRALIA: LACK OF DETAIL BUT APPLY NOW**

*** CHEMGENEX DISMISSES FDA DATA INTERPRETATION**

*** BIOGUIDE BRIEF: CHEMGENEX, THE FDA AND TOUGH QUESTIONS**

*** COCHLEAR RECORD H1 PROFIT UP 8% ON REVENUE DOWN 2%**

*** PHARMAXIS PXS25 PASSES PHASE I; COMPLETES TOPIGEN PURCHASE**

*** COMPUTERSHARE UK RESOLVES STEM CELL PAYMENTS**

*** LIVING CELL TAKES 10% OF US WOUND HEALING COMPANY**

*** USCOM H1 REVENUE UP 13.3% TO $635k, LOSS REDUCED**

*** ELLEX EXPECTS INCREASED EARNINGS**

MARKET REPORT

The Australian stock market fell 0.36 percent on Tuesday February 9, 2010 with the S&P ASX 200 down 16.3 points to 4505.1 points. Eight of the Biotech Daily Top 40 stocks were up, 17 fell, 10 traded unchanged and five were untraded.

Avexa was best, recovering two cents or 18.2 percent to 13 cents with 5.0 million shares traded, followed by Living Cell up 9.1 percent to 18 cents.

Novogen climbed seven percent; Benitec was up four percent; Cochlear and Prima were up more than three percent; Tissue Therapies rose 2.4 percent; with Phosphagenics and Universal Biosensors up more than one percent.

Chemgenex led the falls, down as much as 21.5 cents or 25.4 percent to 63 cents before closing down 16.5 cents or 19.5 percent at 68 cents with 5.6 million shares traded, followed by Antisense down 15 percent to 5.1 cents with 3.5 million shares traded.

Prana lost 9.7 percent; Patrys was down 7.1 percent; LBT fell 6.6 percent; QRX lost five percent; Viralytics fell 4.7 percent; Cathrx, Cellestis, Pharmaxis and Sirtex were down more than three percent; Acrux, Starpharma and Resmed shed more than two percent; with Alchemia, Clinuvel, Genera and Nanosonics down more than one percent.

COMMERCIALISATION AUSTRALIA

The acting chief executive officer of Commercialisation Australia Tricia Berman says despite needing detailed development the funding body wanted applications now.

Ms Berman, who is also the general manager for Innovation Policy in the Department of Innovation, told a well-attended Bio-Melbourne Breakfast that there were a range of issues for Commercialisation Australia to resolve including the composition of the board, a permanent chief executive officer and specific eligibility and funding requirements.

But Ms Berman said that the only way for the Federal Government to know that innovation required more funding than the $82 million a year allocated to Commercialisation Australia was to receive applications demonstrating the need.

One attendee made the point that the Commercial Ready scheme axed by the Federal Labor Government in the 2008 Budget allocated more than $700 million a year and all those applications were on file within the Department of Innovation.

Ms Berman said the details of the Federal Government's Research and Development Tax Credit program were also still being resolved and in answer to a question said until that had been concluded there would not be a clear demarcation between Commercialisation Australia's early stage funding and the benefit for later stage development.

She said she could not comment on whether the Federal Government would fund phase II and II trials.

Ms Berman said there had been many applications for funding from New South Wales and she urged Victoria to file "as many applications as possible".

She said there was "a quantum of money" available for the current financial year and if it was not allocated it would likely be returned to general revenue.

"We have $20 million for this financial year. We are encouraging proposals that are ready to go, Ms Berman said.

"People will look to see is that the right quantum and it depends of the quality of applications. More money could be available," Ms Berman said.

Ms Berman said she expected the board to be announced in March as well as the first assessments of funding.

She said that Commercialisation Australia would be funding companies as they apply rather than at set dates and the board would respond to funding application.

Ms Berman said the competitive and merit based system could provide funding within two months of applications.

The skills and knowledge grants provide from $50,000 to $200,000 for executive and senior staff and are 80 percent government and 20 percent company funded and non-repayable. These grants can be used to offset the cost of hiring staff up to chief executive officer level but are only available if there is no other source of funds.

Ms Berman agreed that there appeared to be a gap between funding proof-of-concept or phase I trials and the requirement of being close to market.

She said that, along with other issues, would be "resolved over the next few months".

Proof-of-concept grants dependent on "commercial viability" and matching funding could range from $50,000 to $250,000 and early stage grants range from $250,000 to $2 million and were "repayable on success", which Ms Berman said was after the first cumulative $100,000 worth of sales of the product and then at five percent of sales.

Major research institutes would be required to have "an eligible partner entity" and one institute executive told Biotech Daily that would be an issue needing to be resolved.

The Department of Innovation's commercialization team manager Donna Valenti told the meeting that institutions could have a unit responsible for commercialiazation or could apply through an eligible partner entity.

Ms Berman said Commercialisation Australia could refer applicants to other programs and would provide voluntary mentors.
She said the Department would fund case managers for each applicant and applicants could apply for any and all of the grants available.
Ms Berman said the pre-application form would be discussed with case managers and the company would then proceed to the final application.
Ms Berman said that there was a clause in the application form requiring acknowledgement of reading the funding contract, which was "going through legal advice" and was also expected to be concluded soon.
Commercialisation Australia is available vi a telephone "hotline" on 13 22 56 or through the website: www.commercialisationaustralia.gov.au.

CHEMGENEX

Chemgenex chief executive officer Dr Greg Collier has dismissed US Food and Drug Administration questioning of efficacy data for Omapro for chronic myeloid leukemia.
In a briefing note to the oncologic drugs advisory committee (ODAC) meeting, the FDA cited Chemgenex primary endpoint result response rates including a 25 percent cytological response for 10 of 40 chronic myeloid leukemia patients with the T315I mutation.
The FDA said it evaluated the source data and reduced the number of cytological responses by two patients which the FDA said were "unconfirmed due to the lack of protocol-required bone marrow aspirations".
The US regulator referred to a number of other points in the data and said the complete haematological responses were "not applicable" in chronic phase patients.
The FDA report is at:
http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/UCM199561.pdf
Dr Greg Collier told Biotech Daily: "We think our data will stand up beautifully".
"That's their interpretation, looking at our data," Dr Collier said.
"What they have said is not set in stone. These are their questions," he said.
Chemgenex chief financial officer and chief operational officer Dr James Campbell said that one of the issues was that the FDA was "only addressing data in the submission of mid last year".
"This is guidance from the FDA to ODAC for the company to answer and we are delighted to do so," Dr Campbell said. "These are the questions the company will address," he said.
In an RBS Morgans briefing note research associate director Tanya Solomon wrote that the issues "are the items one would expect and want the FDA to be focused on".
"It is not uncommon for the FDA to take a hard-line on questions leading into ODAC. It is then up to CXS to address these issues," Ms Solomon wrote.
"We have spoken to the company and reviewed the data independently. We are comfortable with the results to date and that patients with CML and the T315I mutation have few treatment options currently available. That said, the ODAC meeting is not without risk and remains a critical milestone for the company," Ms Solomon said.
The ODAC meeting was scheduled for February 10, 2010 but has been postponed due to severe weather in North America.
Chemgenex fell as much as 21.5 cents or 25.4 percent to 63 cents before closing down 16.5 cents or 19.5 percent at 68 cents with 5.6 million shares traded.

MARC SINATRA'S BIOGUIDE BRIEF: CHEMGENEX

The US Food and Drug Administration has released its briefing document for the oncologic drugs advisory committee meeting to review the data on Chemgenex's Omapro for chronic myeloid leukaemia in patients with the T315I mutation.

In short, after reviewing Chemgenex's data and the medical data collected from the patients on whom it is based, the FDA has produced its own data set.

Most notably, it believes that only six of 40 (15%) patients in the chronic stage of the disease, rather than the 10 of 40 (25%) collated by Chemgenex, demonstrated a major cytogenetic response to treatment with Omapro.

The FDA also did not consider the two of 10 (20%) blast phase patients that responded to treatment according to Chemgenex, to be true responders, leaving Omapro with none of 10 on this count and it appears that Chemgenex's data is much more sparse than hoped.

While not the death of Omapro by any means, it does look like more data will need to be collected. Omapro's saving grace may be that ODAC isn't bound by the FDA's slicing and dicing of the data.

The most impressive piece of data in the Omapro package is that 85 percent of the 40 chronic phase patients studied exhibited a complete haematologic response.

The FDA hasn't considered this point because they don't view haematological responses as a suitable end-point for chronic phase patients.

The medical literature does, however, and I believe ODAC's recommendation will hinge on this point. While the FDA is not bound by ODAC's recommendation, positive or negative, it does generally follow it.

Despite the FDA's aggressive stance toward Omapro's NDA, I still think they will approve it, most likely with some hefty post-approval surveillance requirements.

Marc Sinatra
Analyst

* Marc Sinatra and Biotech Daily editor David Langsam own Chemgenex stock.

COCHLEAR

Cochlear said that its net profit after tax for the six months to December 31, 2009 was up eight percent to $75.2 million.

Cochlear said total revenue was down two percent to $347.6 million but said sales were up four percent in constant currency terms.

In a telephone conference Cochlear chief executive officer Dr Chris Roberts said the high value of the Australian dollar "had a profound effect" on the company's financial data.

Dr Roberts said that using the exchange rate of 12 months earlier the profit figure would have been $22.6 million higher, but said that "FX is what FX is".

Cochlear said it would pay a fully franked interim dividend of 95 cents per share on March 16 2010, a 19 percent increase on the previous corresponding period.

"This financial result was helped by the successful launch of the new Cochlear Baha BP100 sound processor and the next generation cochlear implant system, Cochlear Nucleus 5," Dr Roberts said in the company's media release.

"Customer feedback from the new systems is extremely positive and improved clinical performance demonstrated," Dr Roberts said.

"Importantly, these launches provide momentum going into the second half," he said.

Cochlear said that it expected its net profit after tax for the 12 months to June 30, 2010 would be "at least 15 percent" over the 2008-'09 financial year.

Cochlear was up $2.16 or 3.5 percent to $63.55.

PHARMAXIS

Pharmaxis has completed the first phase I clinical trial in healthy volunteers with its new drug candidate, PXS25 for fibrotic diseases including lung disease.

Pharmaxis said the trial was designed to determine the tolerance and pharmacokinetic profile of PXS25 following intravenous administration.

The company said the trial investigated five ascending doses of PXS25 in 40 subjects and at all doses, PXS25 was found to be safe and well tolerated with a pharmacokinetic profile consistent with a drug that could be delivered once per day.

Pharmaxis chief executive officer Dr Alan Robertson said the company had encouraging results from PXS25 in pre clinical testing that suggests it would be active in a range of fibrotic diseases.

He said that based on the results from the phase I study, “PXS25 fulfils many of the other criteria we look for in a drug”.

Dr Robertson said additional phase I trials would be completed before PXS25 was evaluated in patients with lung disease.

The company said PXS25 was being developed as a potential new treatment for pulmonary fibrosis which has a mortality rate that exceeded many cancers and affected more than five million people worldwide.

Separately Pharmaxis said it had issued 3.2 million shares on completion of the acquisition of Canada-based Topigen Pharmaceuticals Inc (BD: Jan 17, 2010).

An additional 5.0 million shares will be issued subject to the achievement of certain preclinical and clinical milestones specified in the purchase agreement.

Pharmaxis said Topigen had a number of innovative therapeutic candidates for respiratory disorders based on its multi-targeted oligonucleotide technology.

The company said Topigen’s lead drug candidate TPI ASM8 was in phase II clinical development for moderate to severe asthma and a second drug candidate TPI 1100 was in preclinical development for chronic obstructive pulmonary disease.

Pharmaxis fell eight cents or 3.2 percent to $2.44.

LIVING CELL TECHNOLOGIES

Living Cell has received 10 percent ownership of Cytosolv Inc in exchange for restricted supply of choroid plexus cell clusters from its pathogen free pig herd.

Living Cell said it had granted the Rhode Island-based Cytosolv a non-exclusive, non-transferable licence to use its choroid plexus patents for the purpose of wound healing.

The company said Cytosolv was developing technology for wound healing, initially targeting diabetic ulcers, involving the delivery of a mixture of wound-healing factors derived from porcine choroid plexus cells, cultured using proprietary techniques. The cells normally secrete a variety of factors into the cerebrospinal fluid that are responsible for growth, differentiation, nurturing and maintenance of the brain, Living Cell said.

Cytosolv has demonstrated that a topical gel based on a cocktail of these factors accelerates and improves the quality of healing of open skin wounds, and has recently been awarded $US500,000 from the Slater Technology Fund to pursue more advanced pre-clinical development in the year ahead.

Living Cell chief executive officer Dr Paul Tan said that although the collaboration was outside the company’s core business of live cell implants, “the topical use of secreted products from porcine [choroid plexus] cells offers a potential revenue stream from supply of cells and investment return”.

Living Cell was up 1.5 cents or 9.1 percent to 18 cents.

STEM CELL SCIENCES, ASSET REALISATION CO

Computershare UK says its Australian sister company will replace the effectively worthless cheques from the winding up of Stem Cell Sciences as Asset Realisation Co.
Biotech Daily reported the problem last month and Computershare has agreed to replace the Australian dollar, but UK-drawn cheques without an Australian reference bank for Australian cheques (BD: Jan 22, 29, 2010).
Bendigo Bank said it could cash a $150 cheque but would charge $120 to do so as it had to go back to the Royal Bank of Scotland in London to be processed and the Commonwealth Bank said it could not accept that kind of cheque for amounts below $300.
Computershare UK marketing director Lucy Newcombe said in an email the original cheques could be replaced with a cheque drawn on an ANZ account.
Ms Newcombe said there would be “no charge to the shareholder for this service”.
Ms Newcombe said shareholders should forward their existing cheque with a covering letter to Computershare Investor Services, 452 Johnston Street, Abbotsford, Melbourne Victoria 3067, with the envelope clearly marked Asset Realisation Project.
She said that if the existing cheque had been submitted for payment but a shareholder would like to receive a cheque drawn locally on an ANZ account instead, they must contact Computershare at the address above and request that a 'stop' is placed on the original cheque.
Providing the original cheque has not already cleared, Computershare will then be able to issue a replacement cheque.
“However, Computershare, Asset Realisation Company Limited, its joint liquidators and Grant Thornton UK LLP regret that they will not be liable to any claim for charges or fees that may be incurred in relation to the negotiation of the original cheque,” Ms Newcombe said.

USCOM

Uscom’s revenue for the six months to December 31, 2009 was up 13.33 percent to $635,337 with the net loss after tax reduced by 16.55 percent to $830,894.
Uscom was untraded at 74 cents.

ELLEX MEDICAL LASERS

Ellex Medical Lasers says unaudited earnings before interest tax and depreciation for the six months to December 31, 2009 was up 12 percent to $2.9 million.
Ellex said demand weakened during the half year, which resulted in a 16 percent reduction in revenue from the previous comparable period.
The company said “a continued focus on cost reduction strategies and improved operating efficiencies delivered an unaudited profit before tax of $1,735,000, a 107 percent increase over the previous comparable period (excluding non-recurring items).
Ellex said it previously advised on December 17, 2009 that it expected revenue to be down by up to 20 percent from the budget target.
Ellex chief executive officer Simon Luscombe said revenue fell during the period due to recessionary pressures in the US and Europe but Australian and Japanese sales were strong.
Ellex climbed two cents or 12.5 percent to 18 cents.