Biotech Daily

Thursday September 3, 2009

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: PEPLIN UP 52.5%; PHOSPHAGENICS DOWN 4%**

*** LEO PHARMA BIDS $348m FOR PEPLIN; WILL FUND OPERATIONS**

*** BIOGUIDE BRIEF: PEPLIN NOT A 5-BANGER, ANY MORE**

*** FEDERAL GOV, START-UP, STARFISH $10m FOR BIONOMICS, MIMETICA**

*** IMMURON FINALIZES HADASIT TECHNOLOGY ACQUISITION**

*** SIRTEX SIR-SPHERES IMPROVE IRINOTECAN LIVER CANCER TREATMENT**

*** ACRUX BULLISH ON PHASE III TESTOSTERONE RESULTS**

*** CATHRX SIGNS SCANDINAVIA, BALTIC, CENTRAL EUROPE DISTRIBUTOR**

*** USCOM STANDARD-OF-CARE PRESENTATION**

MARKET REPORT

The Australian stock market fell 0.19 percent on Thursday September 3, 2009 with the S&P ASX 200 down 8.6 points to 4429.6 points.

Twenty-two of the Biotech Daily Top 40 stocks were up, six fell, six traded unchanged and six were untraded.

Peplin was best, climbing as much as 35 cents or 58.3 percent to 95 cents and closing up 31.5 cents or 52.5 percent to 91.5 cents with 1.6 million shares traded, followed by Genetic Technologies up 10 percent to 5.5 cents with 12,400 shares traded.

Universal and Uscom climbed more than nine percent; Benitec was up 8.6 percent; Alchemia, Mesoblast and Psivida were up more than seven percent; Prana and Sunshine Heart were up more than six percent; Chemgenex and Tyrian rose five percent or more; Avexa was up 4.55 percent; Circadian, Pharmaxis and Starpharma were up more than three percent; Cochlear, Heartware and Nanosonics rose more than two percent; with Progen and Sirtex up more than one percent.

Phosphagenics led the falls, down 0.5 cents or 4.35 percent to 11 cents with 279,216 shares traded, followed by Living Cell and Phylogica down more than three percent with Genera and Optiscan down more than one percent.

PEPLIN

Peplin says the Denmark-based private dermatology and critical care company Leo Pharma will acquire all of its securities for $US287.5 million ($A348.4 million) in cash.

Peplin said it had a definitive merger agreement with Leo Pharma A/S.

The company said the purchase price translated to $US16.99 per common share of Peplin stock or $A1.03 per Peplin CHESS Depositary Interest (CDI).

The acquisition came as a surprise to the market given previous comments by chief executive officer Tom Wiggans that he expected Peplin to market its lead candidate PEP005 Gel for actinic keratosis and other pre-cancerous lesions (BD: Dec 17, 2008).

Mr Wiggans told Biotech Daily today that the offer was a good deal for his shareholders.

“This is a fantastic product and it would have been very exciting to commercialize it ourselves,” Mr Wiggans said.

“But this is a very good deal for shareholders,” he said.

Peplin said Leo would provide Peplin with access to a loan facility to fund ongoing operations until the transaction closed, which was expected by the end of 2009.

Peplin said the directors of both companies unanimously approved the transaction and that two of its largest stockholders, MPM Capital and GBS Venture Partners, along with Peplin’s directors and executive officers agreed to vote in favor of the transaction, which is subject to approval by Peplin’s stockholders and other conditions.

The company said a stockholder meeting was scheduled to approve the transaction, following any US Securities and Exchange Commission review of the proxy materials.

Mr Wiggans said the company was “delighted to enter into this agreement with Leo, a globally recognized dermatology leader”.

“We are very proud of the accomplishments of the entire Peplin team over the past several years to advance our lead candidate PEP005 Gel for actinic keratosis through to near completion of phase III clinical trials,” Mr Wiggans said.

“We are pleased Leo recognizes the potential of PEP005 Gel as an innovative product for the treatment of actinic keratoses and other skin diseases,” Mr Wiggans said.

The president and chief executive officer of Leo Pharma Gitte Aabo said the Peplin agreement “fits extremely well with our ambition of staying in the global lead within dermatology”.

“We are truly impressed with the amount of work and dedication that the people at Peplin have tied into this project,” Mr Aabo said.

Peplin’s lead product candidate, PEP005 Gel is in phase III clinical trials for actinic (solar) keratosis, a common pre-cancerous skin lesion, on both head and non-head locations.

Peplin expects to complete the phase III actinic keratosis clinical trials by the end of 2009.

Results from its first phase III trial, Region-I, were announced in May 2009 and the company plans to file a new drug application in mid-2010.

Peplin said it had a phase II clinical trial ongoing for PEP005 Gel in superficial basal cell carcinoma and preliminary data in squamous cell carcinoma and cutaneous warts.

Peplin said its CDIs per share purchase price was denominated in US dollars and the price to be paid would fluctuate with changes in the exchange rate.

Leo Pharma said it was wholly owned by the Leo Foundation and was an independent, research-based pharmaceutical company based in Ballerup, Denmark, near Copenhagen.

Leo said it was “one of the world’s leading companies within dermatology and the parenteral treatment of thrombo-embolisms.

In 2008, 96 percent of Leo Pharma’s $US1.1 billion turnover was from outside Denmark.

Peplin climbed as much as 35 cents or 58.3 percent to 95 cents, closing up 31.5 cents or 52.5 percent to 91.5 cents with 1.6 million shares traded.

MARC SINATRA'S BIOGUIDE BRIEF: PEPLIN

I imagine that Leo Pharma's $348 million dollar ($1.03 per CDI) offer for Peplin will be met by the same "low-ball bid" outcry that followed Cephalon's ultimately successful tilt at Arana Therapeutics.

Despite having valued Peplin at just over $3 dollars in late April, I am not sure that the offer is all that bad (BD: Apr 27, 2009).

Two important and linked things have happened between today's offer and my valuation. The first is that in May, Peplin announced the results of its Region-Ia phase III actinic keratosis clinical trial for the treatment of non-head locations (BD: May 18, 2009).

While the results were positive, they were not outstanding.

The complete clearance rate of 27.4 percent didn't really compare favorably to the 44 percent rate found in Peplin's previous PEP005-006 phase IIb study and this difference only marginally improved to 31 percent compared to 45 percent, respectively, when like groups of patients from each study were compared.

The results also didn't compare favorably to the other topical treatments on the market, which have generally shown complete clearance rates of around 45 percent. Peplin's advantage is a much shorter duration of treatment.

The upshot of these results was that in June the US Food and Drug Administration suggested, and Peplin agreed to, a second phase III study of non-head sites, confirming that the Region Ia study results were not great.

If I were a Peplin director these events would certainly make me willing to consider offers I previously wouldn't have countenanced.

Interestingly, Peplin's suitor, Denmark-based Leo Pharma, doesn't have much of a US presence. While it does have an office in Florida, it is there to focus on supporting the company's Latin America operations.

If one takes a worse-case scenario approach and assumes the US regulatory approval is looking less likely than it was previously, Leo Pharma's offer and Peplin's directors' acceptance of it starts to look much more reasonable.

If I were a Peplin shareholder*, I would accept the offer.

While it may not have been what I was hoping for, it is still at a 70 percent premium to Peplin's pre-offer price and, as the saying goes, a bird in the hand is worth two in the bush....or three where my valuation of Peplin is concerned.

Marc Sinatra
Analyst

* The author has previously owned Peplin shares but has not held them for six months.

IIFF - BIONOMICS

Start-up Australia will invest $8.5 million from the Australian Government's Innovation Investment Follow-on Fund in Bionomics and in private Queensland company, Mimetica.
Start-up managing director Dr George Jessup told Biotech Daily that his venture capital investment fund was expected to repay the Government investment and he expected "to return $16 to $24 million for the $8.5 million".
Dr Jessup said he had almost entirely repaid the $20 million previous amount provided by the Government and had retained profits as well as ongoing investments that would also be returned from the Government's initial investment.
He said the investments were "highly competitive" and he would "have to return outstanding profits to the Government".
Dr Jessup said that when the money was repaid, Start-Up Australia was entitled to "a profit share above a hurdle similar to normal venture terms".
Dr Jessup said he was a former director of Bionomics dating back to the company's acquisition of Iliad Chemicals in May 2005.
In its media release to the ASX, Bionomics said it would place $7 million worth of shares with Start-up Australia Ventures as trustee of the Start-up Australia Trust at no more than 25 cents a share.
Start-up's Dr Jessup said he was "delighted with the continued progress of Bionomics".
"The company has two exciting new drugs in clinical trials and a high value partnership with a major European pharmaceutical company," Dr Jessup said.
"They have achieved this with a very efficient use of shareholder funds," Dr Jessup said.
"This new funding will allow the company to achieve critical value adding milestones for investors and is also important for patients who are in need of these drugs," he said.
Bionomics said the placement was conditional on shareholder approval and the company raising a further $5 million through private placements to institutional or sophisticated investors.
Bionomics said it intended to undertake additional private placements as soon as possible to raise the funds to satisfy the second condition and had commissioned the ANZ Bank related and Sydney-based Linwar Securities to manage the placements.
Bionomics was untraded at 24 cents.

IIFF- MIMETICA

Mimetica's chief executive officer Dr Michael Thurn told Biotech Daily that the Start-Up $1.45 million would be matched by a further Innovation Investment Follow-on Fund $1.45 million via Melbourne's Starfish Ventures.
Dr Thurn said the money would be used for the company's first phase I clinical trial testing the safety and efficacy of its "topical small molecule that mimics a peptide" which was being developed as a treatment for acne.
Mimetica is a private unlisted company.

IMMURON

Immuron says it has completed the acquisition of the oral immune modulation technology from Israel's Hadasit Medical Research Services and Development (BD: Apr 21, 2009).
The company said it had executed the required agreements for the development of the technology and Hadasit had become a 19.9 percent substantial shareholder.
Immuron was up 0.1 cents or 1.85 percent to 5.5 cents.

SIRTEX MEDICAL

Sirtex says a clinical trial has shown that SIR-Spheres improve the use of irinotecan-based chemotherapy for inoperable liver metastases from colorectal cancer.

Sirtex said the 25 patient trial was designed to assess the safety and toxicity of this combination and the final results were published with an editorial comment in the current edition of the Journal of Clinical Oncology.

Entitled 'Treatment of Fluorouracil-Refractory Patients With Liver Metastases From Colorectal Cancer by Using Yttrium-90 Resin Microspheres Plus Concomitant Systemic Irinotecan Chemotherapy' the article in the Journal of Clinical Oncology is available at: http://jco.ascopubs.org/cgi/content/short/27/25/4089?rss=1.

Sirtex quoted the article saying that "of the 25 patients in the study, 11 (48%) showed a decrease in the tumor size by at least 30 percent with a further nine (39%) having stable disease, providing a disease control rate of 87 percent".

Sirtex said the median progression-free survival was six months (range 1.6 to 11.4 months), and median progression-free survival in the liver was 9.2 months (range 1.6 to 25.8 months).

Sirtex said the median overall survival was 12.2 months (range 2.8 to more than 60 months), with three patients, all of whom had disease initially confined to the liver, still alive at the time of reporting.

The company said "this data compares favorably to phase II/III studies on irinotecan alone and irinotecan-based chemotherapy regimens".

In a related editorial entitled 'Radioembolization of Liver Metastases in Patients With Colorectal Cancer: A Nonsurgical Treatment With Combined Modality Potential', Ohio's Riverside Methodist Hospital's Dr J Philip Kuebler said SIR-Spheres were "an emerging therapy for patients with unresectable hepatic metastases".

The editorial is at: http://jco.ascopubs.org/cgi/content/full/27/25/4041.

"Given the relative absence of grade 3 to 4 adverse events, van Hazel et al7 conclude quite correctly that the maximum-tolerated dose of irinotecan was not determined and that 100 mg/m2 on days 1 and 8 of a 3-week cycle in combination with 90Y RE is a safe regimen," Dr Kuebler said.

"Of 23 evaluable patients, partial responses at 12 weeks post- treatment were confirmed in 11 patients (48%), and stable disease was confirmed in nine patients (39%). These results seem higher than expected for previously treated patients," Dr Kuebler said.

"Selective internal radiation therapy with 90Y using resin microspheres as a unique delivery vehicle has become a viable option in treatment of liver metastases in patients with colorectal cancer.

"Administration of SIR-Spheres - available in the United States and approved for use with hepatic arterial injection of floxuridine - is complex, requiring pretherapy angiograms to assess liver vascular anatomy and a nuclear study to confirm absence of significant shunting to the lung," he wrote in the editorial.

"Dose calculations are difficult and often include adjustments that are unpredictable and not consistent between patients. Because of the embolization of vessels as microspheres are injected, the delivered dose of radioactivity may be less than the calculated dose," Dr Kuebler said.

Dr Kuebler said there was a need for more data.

Sirtex said the trial was conducted at four Australian centres, with 25 patients who failed first-line chemotherapy, with 40 percent having also failed second or third-line regimens, and 60 percent having failed oxaliplatin-based regimens.

Sirtex was up seven cents or 1.56 percent to $4.55.

ACRUX

Acrux says it will file a new drug application for its Axiron testosterone treatment by the end of 2009, following a meeting with the US Food and Drug Administration.

The company said the results from the phase III open label trial of Axiron would be released during the week beginning September 28, 2009.

Acrux said the trial would be successful if "more than 75 percent of patients have testosterone levels within the normal range" after Axiron treatment.

The company said the safety extension study of 52 patients who were treated with Axiron for six months to monitor skin safety had been completed.

Acrux said it had "strong interest from a number of potential marketing partners for Axiron" and following release of the phase III results, formal partnering discussions would begin in October 2009.

The company said that if Axiron was approved by the FDA, it was expected to enter the $US1 billion testosterone therapy market in early 2011.

Acrux chief executive officer Dr Richard Treagus said he expected "strong interest in the formal partnering process that will commence next month following release of the phase III results".

Acrux was up one cent or 0.75 percent to $1.35.

CATHRX

Cathrx says it has signed a distribution deal with Subito Cardiology for Scandinavia, Central Europe and the Baltic States.

Cathrx said Subito Cardiology was a specialist distributor of cardiac products to electrophysiology labs in the region.

The company's president Ged Wallace said the agreement was "a key element in our sales strategy".

"We now have over 30 sales specialists selling Cathrx products across Europe," Mr Wallace said.

Cathrx was unchanged at 24.5 cents.

USCOM

Uscom presented three papers on its ultra-sonic cardiac output monitor as a standard-of-care to the World Federation of Ultrasound in Medicine and Biology meeting today.

Uscom said the presentation by executive chairman and director of clinical science Rob Phillips at the 12th World Congress in Sydney said the company's monitor should be "a standard-of-care in fluid management, pediatric sepsis, intensive car, organ procurement and liver transplantation".

Mr Phillips gave a presentation entitled 'Uscom: A New Standard for Circulatory Management in Critical Care' citing published literature supporting standard-of-care status for the company's Uscom 1a monitors.

Uscom said Mr Phillips was an invited speaker at the Congress.

Uscom climbed seven cents or 9.3 percent to 82 cents.