Biotech Daily

Wednesday July 4, 2012

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: AVITA UP 11%, PSIVIDA DOWN 16%**

*** STARPHARMA 2013 DENDRIMER-DOCETAXEL CANCER TRIAL**

*** SIRTEX 12-MONTH DOSE SALES UP 23%, IMPLIED REVENUE $86m**

*** CLARIFICATION: OSIRIS TRIAL DATA**

*** VICTORIA $1m FOR OSPREY, BAKER, RMH DIABETIC FOOT INFECTIONS**

*** LATE CONTRACT REDUCES ATCOR REVENUE GUIDANCE**

*** CONSEGNA EXTENDS ASPEN EVALUATION; CANADIAN PATENT**

MARKET REPORT

The Australian stock market climbed 1.09 percent on Wednesday July 4, 2012 with the S&P ASX 200 up 45.0 points to 4,172.2 points.

Nineteen of the Biotech Daily Top 40 stocks were up, eight fell, nine traded unchanged and four were untraded.

Avita was the best, up two cents or 10.8 percent to 20.5 cents with 205,157 shares traded, followed by Viralytics up 10.7 percent to 31 cents with 195,226 shares traded and Circadian up 10.0 percent to 38.5 cents with 20,000 shares traded.

Compumedics, Impedimed and Phylogica climbed more than seven percent; Nanosonics, Phosphagenics and Prana were up more than six percent; Allied Health rose 5.3 percent; Anteo, Neuren, Pharmaxis, QRX, Sirtex and Sunshine Heart were up four percent or more; with Acrux, Cochlear and Mesoblast up by less than one percent.

Psivida led the falls, down 35 cents or 15.6 percent to $1.90 with 100 (one hundred) shares traded.

Genetic Technologies and Prima fell four percent or more; Bioniche shed 2.5 percent; Bionomics, Heartware, Resmed and Tissue Therapies lost more than one percent; with Clinuvel and CSL down by less than one percent.

STARPHARMA

Starpharma says it expects to take its dendrimer version of cancer drug docetaxel to clinical trials in 2013.

In February, Starpharma said that mouse data showed that its dendrimer-docetaxel formulation was “significantly more efficacious” than docetaxel (Taxotere) in a breast cancer model (BD: Feb 1, 2012).

Starpharma said at that time that docetaxel was a leading chemotherapy drug used to treat a wide range of solid tumors including breast, lung and prostate and along with demonstrating a marked improvement in the water solubility of docetaxel its dendrimer-docetaxel formulation demonstrated a significant enhancement of anti-cancer effect.

Starpharma said in February that 60 percent of animals treated with dendrimer-docetaxel had no evidence of tumors at 94 days, compared to all of the docetaxel treated mice showing significant tumor re-growth or recurrence at 94 days.

Today, Starpharma said the strong preclinical data supported clinical trials and the company was scaling-up its dendrimer-docetaxel synthesis to support both further development studies and clinical trials.

The company said it had demonstrated that the plasma half-life of its dendrimer-docetaxel formulation was 60 times longer (30 hours for the dendrimer formulation compared to 30 minutes for Taxotere), which supported the potential for less frequent dosing and was in line with its target product profile for the dendrimer-improved formulation.

Starpharma said its dendrimer technology’s applicability to hormones such as insulin, and antibodies, further diversified drug delivery product potential.

The company said it had successfully formulated its dendrimers with chemotherapeutic drugs including platinum compounds gemcitabine, paclitaxel (Taxol), methotrexate and doxorubicin.

Starpharma said that advancing its drug delivery program had been facilitated by running parallel internal and big pharma-partnered development projects.

The company said that “with many leading drugs either off-patent or nearing the end of patent lifetimes, [its] technology offers a significant opportunity to develop a range of new and improved formulations which can be the basis for new patents” and carried lower development risk than developing completely new products.

Starpharma chief executive officer Dr Jackie Fairley said the company was investigating opportunities to broaden its program and target high value, market leading drugs.

“The evidence supports a high likelihood of Starpharma being able to enhance their properties, or widen their areas of application though the use of dendrimers,” Dr Fairley said. “Other priority targets, apart from docetaxel, include the major chemotherapeutics including a class of widely used, but highly toxic platinum anticancer drugs, which include carboplatin and oxaliplatin.”

“We have also successfully formulated the leading oncology drug gemcitabine with our dendrimers,” Dr Fairley said.

“In addition, Starpharma has recently demonstrated the ability of dendrimers to conjugate to certain therapeutic antibodies, thus opening up the possibility of entering the very exciting field of antibody-drug conjugates,” Dr Fairley said.

Starpharma said that dendrimers could be formulated with hormones such as insulin and testosterone and a highly water-soluble dendrimer testosterone could permit the use of narrower and less painful needles as well as extend duration of activity.

Dr Fairley said the $US1.5 billion global testosterone replacement market was dominated by transdermal products but injectables did not have concerns with secondary exposure and remained important for certain settings and geographies.

Starpharma was up nine cents or 6.4 percent to $1.49.

SIRTEX MEDICAL

Sirtex says dose sales of SIR-Spheres have increased 26 percent for the three months to June 30, 2012 and 23 percent for the full year.

Sirtex did not disclose the value nor the quantity of the sales but last year posted revenue for the 12 months to June 30, 2011 was up 1.2 percent to $72,954,000 with net profit after tax down 28.6 percent to $11,479,000 (BD: Aug 25, 2011).

Sirtex said last year that Sir-Spheres dose sales for the 12 months to June 30, 2011 was 4,977 doses, with product revenue $70.3 million, implying that the company sold about 6,122 doses for the year to June 30, 2012 and, with a lower Australian dollar, product revenue should be about $86 million.

Today, Sirtex said US sales of the targeted radioactive liver cancer treatment microspheres was up 31 percent for the three months and 32 percent for the year

The company said Asia Pacific sales were up 48 percent for the quarter and 37 percent for the year, with European sales up 11 percent for the quarter and four percent for the year.

Sirtex chief executive officer Gilman Wong said the “fourth quarter result continues our successful history and now extends dose sales growth to 32 consecutive quarters”.

“Whilst this is a very good result, our current sales still represent less than one percent of the addressable global market of people diagnosed annually with liver cancer,” Mr Wong said.

“This means that Sirtex still has significant growth potential once the results of some of our clinical studies become available in the next few years,” Mr Wong said.

“We therefore continue to make appropriate investments in the company to ensure the business is in a strong position to take advantage of this potential growth,” Mr Wong said.

“In the meantime we believe we can continue to deliver consistent growth of SIR-Spheres microspheres and build a robust sustainable business,” Mr Wong said.

Sirtex was up 26 cents or 4.2 percent to $6.45.

OSIRIS

In last night’s article on the Allied Health and the Commonwealth Scientific and Industrial Research Organisation stem cell collaboration for heart failure, Biotech Daily quoted what appeared to be positive results from the Columbia Maryland-based Osiris Prochymal 220-patient acute myocardial infarction trial (BD: Jul 3, 2012).

A close reading of the trial design at www.clinicaltrials.gov shows that the trial of the Osiris allogeneic or off-the-shelf stem cells began in March 2009 and was completed in December 2011, indicating slow recruitment and a long wait for what Osiris called ‘preliminary data’.

The trial design specified a primary endpoint of left ventricular end systolic volume and secondary endpoints of left ventricular ejection fraction, infarct size and major adverse cardiovascular events.

http://www.clinicaltrials.gov/ct2/show/NCT00877903?term=prochymal&rank=7.

The Osiris media release said “Prochymal significantly reduces hypertrophy, arrhythmia and progression to heart failure in patients suffering a heart attack” but did not directly address the listed endpoints, instead citing other measures.

Osiris said that “Serious adverse events occurred with equal frequency in both treatment groups (31.8%). To date, there have been five deaths in the trial, two in the Prochymal group and three in the placebo group.”

Last year’s smaller Mesoblast trial had three deaths of 15 controls and one death in the 45 people treated with its mesenchymal precursor cells.

OSPREY MEDICAL

Osprey says the Victorian Government has granted $1.1 million for a first-in-man study of its percutaneous limb perfusion technology.

Osprey said the technology enabled the localized delivery of high dose antibiotics to the lower limb in patients with diabetes with life or limb threatening foot infections.

The company said the funds were provided by the Victorian Government's Market Validation Program.

Osprey said the limb recovery system leveraged its Cincor technology designed to reduce kidney injury from x-ray dyes used during heart procedures and would allow clinicians to use existing antibiotic therapies "in a more targeted and aggressive manner".

The company said the technology was developed at Melbourne's Baker IDI Heart and Diabetes Institute by Prof David Kaye and Dr Melissa Byrne and enabled the circulation of the limb to be isolated and separated from the general circulatory system, permitting the delivery of antibiotic drugs at high doses otherwise unachievable by creating an artificial circuit by inserting catheters into the major artery and vein of the lower limb.

The company said that more than 360 million people worldwide had diabetes and the number was expected to increase by more than 50 percent by 2030.

Osprey said that people with diabetes were prone to diabetic limb and foot infections due to insufficient blood flow and impaired wound healing and standard oral or intravenous delivery of antibiotics was often ineffective in these patients because dosage levels could not be achieved at a sufficient level at the site of the limb infection.

Osprey said that infections of the lower limb were the leading cause of amputations, leading to increased rates of hospitalization and higher healthcare costs.

Osprey chief executive officer Mike McCormick said the funds from the Market Validation Program "will allow us to conduct a two part, sequential human clinical study for our technology".

"The first part will be a pilot clinical study involving five patients to evaluate the safety and tolerability of Osprey's limb recovery system," Mr McCormick said. "The second part will be a randomized clinical outcomes study in 20 patients comparing the effectiveness of our approach with standard dose intravenous delivery of antibiotic therapy."

Osprey said it would partner with the Royal Melbourne Hospitals' Diabetic Foot Unit for the two year study.

Osprey was untraded at 39 cents.

ATCOR MEDICAL

Atcor says that an expected large pharmaceutical company contract has not been finalized in time to be recognized in the 2011-'12 financial year.

Atcor said that as a result, it expected that reported sales "on a constant currency basis" would show a modest contraction compared to the prior year.

The company said that it was confident the contract for its non-invasive Sphygmocor measure of central blood pressure and arterial stiffness, would be concluded shortly.

Atcor chief financial officer Peter Manley told Biotech Daily that previous revenue guidance was for 10 percent to 20 percent above last year's $7,458,000 and would be below that figure.

Atcor chief executive officer Duncan Ross said the company was "disappointed that this pharma contract has taken longer to complete than expected though management remains confident that it will be signed and enacted soon".

The company said the delay had no significant impact on forecast cash flow for 2012-'13.

Atcor was untraded at six cents.

CONSEGNA GROUP

Consegna says it has extended its evaluation period of the Aspen Medisys to pursue interest from European parties for its thermotherapy platform technology portfolio.

Consegna said it acquired Aspen Medisys in December 2011 with the intention of extracting maximum value for shareholders from its nano-particle thermotherapy platform technology, which has shown promise as a treatment for cancer (BD: Jan 22, 2012).

The company said that under the acquisition agreement for Aspen Medisys, it had six months to evaluate the technology and that had been extended by 120 days to October 29, 2012.

Consegna said the Aspen Medisys vendors accepted the extension with a deposit payment in scrip of $141,000 to be paid with the balance of shares should Consegna agree to complete the acquisition.

The company said the Canadian Patent Office had allowed a patent entitled 'Thermotherapy via Targeted Delivery of Nanoscale Magnetic Particles' which was a key patent in the portfolio and followed the granting of the patent in the US.

Consegna was untraded at 1.8 cents.