Biotech Daily

Wednesday July 25, 2012

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: BIONICHE UP 19%, PATRYS DOWN 14%**

*** CE MARK FOR SUNSHINE HEART C-PULSE AORTA CUFF PUMP**

*** US PATENT FOR HATCHTECH; PHASE II DATA PRESENTATIONS**

*** ACTINOGEN ACTINOMYCETES FOR TAMIFLU'S SHIKIMIC ACID**

*** SIRTEX PRACTITIONERS DISCUSS SIR-SPHERE EFFICACY**

*** PHARMAXIS APPOINTS DR SIMON BUCKINGHAM DIRECTOR**

*** VIRALYTICS LOSES M-D BRYAN DULHUNTY FOR COMMERCIALISATION**

MARKET REPORT

The Australian stock market closed down 0.22 percent on Wednesday July 25, 2012 with the S&P ASX 200 down 9.3 points to 4,123.9 points.

Eight of the Biotech Daily Top 40 stocks were up, 16 fell, eight traded unchanged and eight were untraded.

Bioniche was the best, up 7.5 cents or 19.0 percent to 47 cents with 155,804 shares traded, followed by Genetic Technologies up 15 percent to 11.5 cents with 70,000 shares traded and Prana up 10 percent to 16.5 cents with 73,500 shares traded.

Sunshine Heart climbed 8.3 percent; Benitec was up 5.9 percent; Biota, CSL and Sirtex were up more than one percent; with Mesoblast up 0.85 percent.

Patrys led the falls, down 0.3 cents or 13.6 percent to 1.9 cents with 1,000,000 shares traded.

Viralytics lost 7.4 percent; Genera and Living Cell were down more than five percent; both Impedimed and Prima fell four percent; Starpharma lost 3.1 percent; Acrux and Psivida shed more than two percent; Alchemia, Anteo, Bionomics, Circadian, and Tissue Therapies were down more than one percent; with Cochlear, Pharmaxis, QRX and Resmed down by less than one percent.

SUNSHINE HEART

Sunshine Heart says it has received Conformité Européenne (CE) mark approval for its C-Pulse heart assist system for class III and ambulatory class IV heart failure.
Sunshine Heart said the approval allowed for commercialization of the technology in Europe and countries in Asia and Latin America that recognize the CE mark.
The company said that the class III heart failure population was about 3.7 million patients in the European Union, with limited and often unsuccessful treatment options.
Sunshine Heart chief executive officer Dave Rosa said the approval was “another significant milestone”.
“The CE mark approval includes our second generation driver, cuff and other components which we believe will improve the overall device performance and ultimately patients’ quality of life,” Mr Rosa said.
Mr Rosa said the company expected to complete the second generation driver evaluation in Canada by October 2012 and then “take a targeted approach to initiate select centers in Europe to participate in a post-market clinical trial that we expect will generate data for reimbursement coverage and to provide additional confirmation of performance”.
Sunshine Heart was up 0.4 cents or 8.3 percent to 5.2 cents with 6.3 million shares traded.

HATCHTECH

Hatchtech says the US Patent and Trademark Office has granted a patent covering a key element of its Deovo head lice treatment.
Hatchtech said the granted US patent described the ovicidal effect through the inhibition of egg hatching of the active ingredient of Deovo and encompassed related compounds.
The company said that further patent applications on other aspects of Deovo were pending in the US and other jurisdictions.
Hatchtech said that chief scientific officer Dr Vern Bowles presented data from its phase IIb clinical trial at the Society for Pediatric Dermatology meeting in Monterey California, July 11-14, 2012 (BD: Dec 16, 2011)
The company said that further clinical efficacy and safety data on Deovo had been accepted for presentation at the American Academy of Pediatrics annual conference in New Orleans, Louisiana, October 20-23, 2012.
Hatchtech chief executive officer Dr Ross Macdonald said the granted US patent was “a very important commercial milestone for Hatchtech.
Dr Macdonald said that equally important was the opportunity to showcase the efficacy and safety data from the phase II studies at two key US conferences.”
Hatchtech said it expected its pivotal US phase III trials to begin in 2013.
Hatchtech is a private company.

ACTINOGEN

Actinogen says it has discovered a series of actinomycetes that can produce shikimic acid, a main component in demand for the production of influenza drug, Tamiflu.
Actinogen has been developing the use of actinomycetes for antibiotics and anti-fungals and more recently bio-fuels (BD: No 9, 2011).
Today, Actinogen said Tamiflu production was complex and one of the most expensive components was shikimic acid, but it could produce shikimic acid from actinomycetes grown at room temperature in aerobic conditions.
Actinogen was up half a cent or 16.7 percent to 3.5 cents.

SIRTEX MEDICAL

Sirtex has hosted technical presentations on the use and potential of its SIR-Spheres radiation microspheres for secondary liver cancer.

In Melbourne today, Sirtex medical director Dr David Cade told about 30 investors and analysts that not all cancer therapies such as surgery, chemotherapy, radiation and biologic therapy were appropriate for all liver cancer patients.

Dr Cade said that SIR-Spheres could be injected in the hepatic artery and flow close to tumor sites, reducing potential damage to healthy liver tissue, which were separately fed through the portal vein to the liver.

Royal Melbourne Hospital consultant medical oncologist and lead investigator in the Sirtex Sirflox trial Prof Peter Gibbs said he had been an early adopter of SIR-Spheres and treated the mother of a colleague in 2002.

Prof Gibbs said that 10 years later the patient remained in remission, alive and well.

Prof Gibbs said that he had treated more than 100 patients with SIR-Spheres and although there were potential problems with radiation-induced gastric ulcers and “a lot of ways it can go wrong”, the therapy had fewer adverse events than existing treatments.

Prof Gibbs said that although there was nausea, fever and pain associated with the treatment, those effects could be ameliorated and SIR-Spheres were a single treatment, whereas chemotherapy also caused significant adverse events and had to be repeated.

Prof Gibbs said that standard radiation treatment was not suited for metastatic liver cancer as other organs could be damaged.

Prof Gibbs cited a 70-patient trial in which SIR-Spheres increased time to liver cancer progression from 9.7 months to 15.9 months and a 21-patient trial extending survival from 12.8 months to 29.4 months.

The briefing was told the 450-patient phase III Sirflox trial of SIR-Spheres in combination with first-line chemotherapy was expected to be completed in 2013, with results in 2014.

Prof Gibbs said there were challenges to the uptake of SIR-Spheres among oncologists including changing treatment options, training in the administration of the microspheres and the time it took to organize the treatment.

Prof Gibbs said that the results of the Sirflox trial and a second trial called Foxfire would have an impact on the way oncologists viewed the treatment.

The head of intervention radiology at Sydney’s St Vincent’s Hospital Prof Lourens Bester said that the beta-radiating SIR-Spheres were safe to use in hospitals and could be suitable in first-line treatment through to salvage treatment.

Prof Bester said that surgery was the only curative option but only five to 15 percent of patients were suitable for surgery.

Prof Bester said five to 15 percent of patients did not respond to SIR-Spheres but 85 percent to 95 percent did respond.

He cited a 57-year old woman who had survived 23 months compared to the expected 6.4 to 10.7 months and a 60-year old male who had survived 34 months and was still alive.

Prof Bester said that cancer patients treated with standard of care and SIR-Spheres had a 12 month survival compared to 6.3 months for standard of care alone; and colorectal cancer patients treated with standard of care and SIR-Spheres had an 11.9 month survival compared to 6.6 months for standard of care alone.

Prof Bester said that SIR-Spheres showed a clear benefit for both groups.

Sirtex chief executive officer Gilman Wong told the meeting that the company “expects a step-change in the use of SIR-Spheres once we have the results of Sirflox and other studies” and the technical briefing was in response to questions from previous investor briefings, which were generally commercial in focus.

Sirtex was up nine cents or 1.4 percent to $6.49.

PHARMAXIS

Pharmaxis says pharmaceutical executive Dr Simon Buckingham has been appointed as a director.

Pharmaxis said Dr Buckingham had more than 20 years experience in pharmaceutical and biotechnology companies with expertise in general management, sales and marketing, clinical development, business development and corporate strategic planning.

The company said that Dr Buckingham had worked in a range of therapeutic areas including cardiovascular and respiratory medicine.

Pharmaxis said that most recently, Dr Buckingham was the head of corporate and business development at the Switzerland-based Actelion and remains affiliated with that company through a senior advisory role.

The company said that prior to Actelion, Dr Buckingham was with Roche.

Dr Buckingham holds a Bachelor of Veterinary Science for the University of Sydney and a Doctor of Philosophy from the University of Melbourne.

Pharmaxis fell one cent or 0.9 percent to $1.10.

VIRALYTICS

Viralytics says managing director Bryan Dulhunty resigned today as it moves from research and development to “accelerating potential revenue generating opportunities”.

Viralytics director Peter Molloy told Biotech Daily that Mr Dulhunty would remain a consultant to the company which would focus “on a strategy towards a pharmaceutical company deal” for Cavatak which was in a US phase II melanoma trial (BD: Oct 20, 2011).

In a media release, the company said it had made “significant progress in value enhancing clinical trials and has maintained a strong cash position”.

Viralytics said that chairman Paul Hopper would become executive chairman while to company conducted a search for a chief executive officer.

Mr Hopper said that since his appointment as managing director, Mr Dulhunty “played an integral role in the effective corporate restructure of the company, establishing an efficient and successfully funded business model and overseeing the enhancement of its valuable intellectual property portfolio”.

Formerly the executive chairman, Mr Dulhunty conducted a major restructure of Viralytics including disentangling it from a substantial CBio shareholding (BD: Jul 17, 2008).

Viralytics said that Sarah Prince had been appointed company secretary, effective immediately and that both Ms Prince and the incumbent company secretary, Tom Rowe, worked as solicitors for Company Matters Pty Ltd.

“We see these changes as offering a real springboard for future growth and for the company’s ongoing successes to be better reflected in its share price performance,” Mr Hopper said

Viralytics fell two cents or 7.4 percent to 25 cents.