Biotech Daily

Wednesday September 9, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: AVITA, ORTHOCELL UP 13%; CIRCADIAN DOWN 5%**

*** GORDAGEN PHASE I MELT3 TABLET SAFETY, BIOAVAILABILITY**

*** ANTISENSE DOSES 300mg ACROMEGALY PATIENTS**

*** ONCOSIL BRACHYTHERAPY CE MARK REVIEW**

*** NUSEP RAISES $267k, DIRECTOR ANDREW GOODALL DILUTED TO 38%**

*** AUSTRALIAN ETHICAL TAKES 5% OF SOMNOMED**

*** IQ3 APPOINTS DAVID BATISTA FOR US INVESTMENT BANKING**

MARKET REPORT

The Australian stock market climbed 2.07 percent on Wednesday September 9, 2015 with the ASX200 up 105.9 points to 5,221.1 points.

Twenty-five of the Biotech Daily Top 40 stocks were up, seven fell, five traded unchanged and three were untraded.

Avita was the best, up 0.8 cents or 12.9 percent to seven cents with 177,348 shares traded, followed by Orthocell up 12.87 percent to 57 cents with 285,988 shares traded.

Living Cell climbed 11.4 percent; Genetic Technologies and Oncosil were up more than nine percent; Compumedics, Impedimed and Prima rose more than six percent; Acrux and Nanosonics were up more than five percent; Atcor, Benitec, Medical Developments, Neuren and Optiscan climbed four percent or more; Prana, Starpharma and Tissue Therapies were up more than three percent; Actinogen and Clinuvel rose two percent or more; with Bionomics, Cochlear, CSL, IDT, Psivida, Sirtex and Universal Biosensors up more than one percent.

Circadian led the falls, down one cent or five percent to 19 cents with 353,582 shares traded. Osprey lost 2.9 percent; Admedus, Anteo, Biotron and Reva shed more than one percent; with Mesoblast and Resmed down by less than one percent.

GORDAGEN PHARMACEUTICALS

Gordagen says it has achieved the primary endpoints of its 60-patient phase I Melt3 study confirming bioavailability, good plasma levels, dose relationship and duration.

Gordagen said that the single ascending dose pharmacokinetic study confirmed the “melt-then-swallow … annatto-derived tocotrienols” Melt3 tablets were easy to take, palatable and well tolerated.

Gordagen chief executive officer Dr Glenn Tong told Biotech Daily that the Melt3 tablets “provide a platform for delivery of tocotrienols as either a dietary supplement or prescription medicines”.

Tocotrienols are part of the vitamin E family along with tocopherols.

In a media release Dr Tong said the completion of the first part of the phase I clinical trial was “a major milestone in our product development program for evidence-based ‘nutraceuticals’.”

“Results from this recent trial provide strong support for the benefits of our Melt3 tablets as a new proprietary and patent-pending tocotrienol formulation that is close to commercial launch in the US and also demonstrate safety and tolerability among healthy volunteers,” Dr Tong said.

Dr Tong said that the data and general information from the studies would assist the efficient design and execute of the prescription pharmaceuticals program, targeting large market opportunities, such as cardiovascular disease and diabetes.

Gordagen said that the study showed that the most clinically-relevant arm comprising subjects not fed a high-fat and high-calorie meal, saw the bioavailability of Melt3 trending above that of orally administered tocotrienols and at the 40mg dose, the mean maximum plasma concentration for the Melt3 arm was 70.9ng/mL of delta tocotrienol isomer, compared to 54.5ng/mL for the oral arm.

Gordagen said a trend was also observed where feeding subjects with a high-fat and high-calorie diet increased the bioavailability of both the Melt3 and oral arms, with the oral arm achieving 254ng/mL for the delta tocotrienol isomer, compared with 168ng/mL for Melt3.

The company said it did not considered this result to be clinically-relevant “due to the unlikelihood of healthy, exercise conscious users consistently consuming high amounts of fat while also taking exercise supplements”.

Gordagen said that a clear dose response relationship was observed and the duration in plasma of about 12 hours, could have a positive impact on dosing, with an additional pharmacokinetic study was planned to focus on the elimination phase of the pharmacokinetic profile and whether less frequent dosing might still achieve efficacy.

Gordagen said that the safety endpoint was achieved with Melt3 observed as very well tolerated and the tablets were found to be easy to administer and palatable.

The company said that the results would form an integral part of its regulatory affairs and market entry program.

Gordagen said that the multiple ascending dose pharmacokinetic study and phase II efficacy studies planned for late 2015 and 2016 would also provide additional information with regard to an effective dosing regimen.

Gordagen chief operating officer Dr Ric DeGaris said that the results from the phase I trial “indicates that the Melt3 product is very promising indeed and lays a solid foundation for both the second part of the phase I clinic trial, the multiple ascending dose [pharmacokinetic] study and also the phase II clinical studies for muscle recovery and exercise endurance”.

Gordagen said it was progressing negotiations with manufacturing, marketing and distribution partners in the US and Japan.

Gordagen is a private company.

ANTISENSE THERAPEUTICS

Antisense says two of four patients have been dosed in its higher dose study of ATL1103 for acromegaly, licenced to Strongbridge Biopharma Plc, formerly Cortendo.

In March, Antisense said the open-label study would examine the safety, tolerability, pharmacokinetics and efficacy, measured by the effect on serum insulin like growth factor I of ATL1103 in adult patients with acromegaly dosed twice weekly with ATL1103 at 300mg for 13 weeks, or 600mg per week, with two months follow up (BD: Mar 5, 2015).

In May, Antisense said that the then Trevose, Pennsylvania-based Cortendo would pay an upfront fee of $6.2 million, with $3.7 million in cash and buy $2.5 million in shares, and up to $131 million for the rights to ATL1103 for endocrinology applications, including acromegaly (BD: May 15, 2015).

Today, Antisense said that dosing was expected to be completed by the end of the year and the reporting of results would depend on the enrolment and the medication status of the additional patients required to complete the trial.

The company said that patients recruited for the study were screened to confirm eligibility during a 28 day period and might need to washout any current acromegaly medications for a period of six weeks to four months, depending on the type of medication, before dosing with ATL1103 may begin.

Antisense said that the ATL1103 higher dose study would run in parallel with other activities to be conducted by Strongbridge, which included seeking orphan drug designation from the US Food and Drug Administration and the European Medicines Agency, the conduct of phase III enabling chronic toxicology studies and a pre-investigational new drug application meeting with the FDA by the end of 2015 to discuss requirements for entry into phase III clinical development.

The company said that its costs associated with the higher dose study would be reimbursed by Strongbridge as part of the May licencing agreement.

Antisense said that Strongbridge was responsible for the clinical development of ATL1103 in endocrinology applications and would fund the associated future development, regulatory and drug manufacture costs.

Antisense was untraded at 7.9 cents.

ONCOSIL MEDICAL

Oncosil says its European notified body the British Standards Institute has confirmed a Conformité Européenne (CE) mark fast-track review has been scheduled for October.

Oncosil said that the review following the submission of the CE mark design dossier for pancreatic and primary liver cancer on July 17 and would assess the dossier and make a recommendation in respect of the CE mark for its silicon and phosphorous brachytherapy.

The company said the review in Birmingham UK would begin on October 6, 2015 and take four days and when completed the notified body would make a determination to either recommend the granting of CE mark certification or ask the company to provide additional information for CE mark certification.

Oncosil said that the CE mark would facilitate commercialization and sales in other markets, including Australia, Canada, and Singapore.

Oncosil chief executive officer Daniel Kenny said that the filing was “the culmination of an intensive eight months of work by the technical team”.

“We now look forward to meeting with the regulator and to securing CE mark for Oncosil and being in a position to offer a new treatment option for the dreaded diseases of pancreatic cancer and liver cancer,” Mr Kenny said.

Oncosil was up 0.9 cents or 9.4 percent to 10.5 cents with 1.5 million shares traded.

NUSEP

Nusep director Andrew Goodall says he has increased his shareholding from 91,882,704 shares to 94,638,261 shares but has been diluted to 38.24 percent.
Mr Goodall said that he held an indirect interest in Nusep through Marjorie Goodall, Ti Rakau Developments and Aemagood Pty Ltd.
Mr Goodall said the parties acquired shares in the recent capital raising at 2.7 cents a share.
On September 3, 2015, Nusep said in announcements to the ASX entitled 'Appendix 3B' and 'Cleansing Notice' that its share purchase plan raised $266,950 through the issue of 9,887,044 shares (BD: Aug 8, 2015).
Nusep fell 0.4 cents or 15.4 percent to 2.2 cents.

SOMNOMED

Australian Ethical Smaller Companies Fund says it has become a substantial shareholder in Somnomed with 2,681,250 shares (5.25%).
Australian Ethical said it bought and sold shares between May 22 and September 1, 2015 with the largest trades a sale and purchase between two of its own trusts of 75,000 shares for $198,750 or $2.65 a share.
The company did not detail its major purchases.
Somnomed was up one cent or 0.4 percent to $2.46.

IQ3 Corp

IQ3 says it has appointed David Batista to head the US investment banking operations of its New York-based subsidiary IQ Capital LLC.
IQ3 said that Mr Batista had more than 20 years of diversified capital markets experience as an investment banker and trader, with US-Australia cross-border experience in capital raising, strategic advisory and financial advisory.
The company said that Mr Batista held a Bachelor of Science in business administration and a Certificate in International Marketing from the New York based CW Post Campus of Long Island University.
IQ3 was up two cents or 7.1 percent to 30 cents.