Biotech Daily

Monday August 15, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: LBT UP 38%, LIVING CELL DOWN 16%**

*** STARPHARMA READY FOR PHASE II BACTERIAL VAGINOSIS TRIAL**

*** GI DYNAMICS $95m IPO FOR DISPUTED PATENT WEIGHT LOSS SLEEVE**

*** FOUNDER, ADVERSARY DR BRUCE GRAY DROPS BELOW 20% IN SIRTEX**

*** CLOVER, CSIRO TO DEVELOP ENCAPSULATION TECHNOLOGY**

*** HELICON BUYS OZPHARMA'S LINGUET BUCCAL TABLET TECHNOLOGY**

MARKET REPORT

The Australian stock market was up 2.64 percent, on Monday August 15, 2011 with the S&P ASX 200 up 110.3 points to 4282.9 points.

Nineteen of the Biotech Daily Top 40 stocks closed up, 11 fell, four traded unchanged and six were untraded. All three Big Caps were up.

LBT was the best, up 1.4 cents or 37.8 percent to 5.1 cents with 675,000 shares traded, followed by Optiscan up 18.2 percent to 13 cents with 253,945 shares traded, Antisense up 16.7 percent to 0.7 cents with 3.9 million shares traded and Virax up 10 percent to 2.2 cents with 30,000 shares traded.

Alchemia climbed 8.6 percent; Genera was up 7.1 percent; Mesoblast rose 6.2 percent; Acrux and Prima were up more than five percent; Cochlear, Heartware and Phosphagenics rose more then four percent; Pharmaxis, Prana and Starpharma were up more than three percent; Bionomics, Nanosonics, QRX, Resmed and Universal Biosensors rose two percent or more; with Anteo up 1.4 percent and CSL up 0.55 percent.

Living Cell led the falls, down one cent or 15.6 percent to 5.4 cents with 257,350 shares traded, followed by Allied Health down 13.8 percent to five cents with 1.7 million shares traded.

Viralytics lost 5.4 percent; Phylogica fell 4.4 percent; Benitec and Clinuvel were down more than three percent; Biota and Genetic Technologies shed more than two percent; with Impedimed, Patrys and Tissue Therapies down more than one percent.

STARPHARMA HOLDINGS

Starpharma says it is ready to begin its 200-patient, US phase II study of Vivagel for the prevention of bacterial vaginosis in women with a prior history of disease recurrence.

Starpharma said that following ethics approval the first patient was expected to be enrolled later this month and the prevention trial was the second area of investigation of Vivagel for bacterial vaginosis.

In May, Starpharma said its 132-patient dose-ranging phase II trial of Vivagel for bacterial vaginosis demonstrated efficacy of the 1% dose, resulting in 74 percent of patients achieving clinical cure two to five days after completion of therapy compared to 22 percent in the placebo group (p = 0.0002) (BD: May 23, 2011).

The company said at that time that two to three weeks after completion of therapy, 46 percent of patients achieved clinical cure of bacterial vaginosis compared to 12 percent for the placebo (p = 0.006).

Today, Starpharma said the phase II prevention trial would be a double-blind, multi-center, randomized, placebo-controlled, dose-ranging study to determine the efficacy and safety of Vivagel or SPL7013 Gel administered vaginally to prevent bacterial vaginosis recurrence.

The company said the trial would assess the efficacy of 1% and 3% doses, used every second day for 16 weeks, in reducing the rate of recurrence of bacterial vaginosis, with the primary endpoint the recurrence of bacterial vaginosis by or at the end of treatment at week 16.

Starpharma said the secondary endpoints were to determine the safety and tolerability of the two doses, assess the acceptability of treatment and characterize the distribution of times to recurrence of bacterial vaginosis.

The company said that discussions with the US Food and Drug Administration and other regulators would be held over the next few months, with phase III studies for bacterial vaginosis treatment expected to begin “in late 2011 or early 2012”.

Starpharma said that the study would be conducted under an investigational new drug application and while the duration of use was 16 weeks, it was intended that women would use the product as a long-term prevention tool, if proven effective.

The company said the global market for topical bacterial vaginosis treatments was estimated at $US350 million and its modeling suggested the addressable global market for prevention of recurrence was more than $1 billion.

Starpharma chief executive officer Dr Jackie Fairley said there were “very few proven options for women who wish to prevent recurrence of [bacterial vaginosis]”

“Clinical experts in this field have repeatedly expressed the need for products to prevent the recurrence of this condition and so the commencement of this program is an important step in the development of Vivagel and the management of the condition,” Dr Fairley said.

Dr Fairley said the phase II results reported in May “included high rates of cure and rapid resolution of symptoms together with excellent patient acceptability”.

The company said that bacterial vaginosis was caused by a disruption to the balance of the vaginal bacteria, so that the bacteria that help maintain a healthy vagina are reduced and harmful bacteria overgrow.

Starpharma said the symptoms of bacterial vaginosis include irritation, discharge and odor with recurrence common following treatment with antibiotics and bacterial vaginosis was associated with pelvic inflammatory disease and pre-term births and several studies found an association between bacterial vaginosis and acquisition of HIV, with one study indicating that more than 30 percent of HIV infections in women could be prevented if bacterial vaginosis was successfully treated.

Starpharma was up 4.5 cents or 3.4 percent to $1.38.

GI DYNAMICS

GI Dynamics is hoping to raise up to $95 million through the issue of up to 104,500,004 CDIs at $1.10 each for its Endobarrier gastric sleeve device with disputed ownership.
The Lexington Massachusetts-based GI Dynamics said the initial public offer of Chess Depositary Interests (CDIs) through lead manager Inteq and lead broker Bell Potter Securities was for “a breakthrough treatment for type 2 diabetes and obesity”.
The company said it was offering up to 72,727,275 CDIs to raise up to $80 million with oversubscriptions to $15 million.
GI Dynamics said it had 40,796,603 shares prior to the offer, equivalent to 203,983,015 CDIs and expected to have a market capitalization of $304,381,319 following the offer.
GI said the Endobarrier was a device implanted non-surgically through the mouth and without cutting any tissue.
The company said the 60cm sleeve was placed into the intestines acting as a barrier between food and the part of the intestinal wall where it was present, to control glucose levels and lose weight at the same time.
GI said the device was implanted in less than 30 minutes and remained in the body for up to 12 months and could be removed in a non-surgical procedure of about 15 minutes.
GI said safety and efficacy had been demonstrated in 13 human clinical trials with more than 500 patients, was granted Conformité Européenne (CE) mark approval in 2010 and sales of the Endobarrier began in Europe and South America in 2011.
The company said it planned to expand in Australia where it received regulatory approval in July 2011, Brazil and the US as regulatory approvals were obtained.
But the company also said that it was engaged in US litigation brought by supplier WL Gore & Associates Inc which supplied the material used to manufacture the liner used in its products including the Endobarrier.
GI said Gore was claiming it was the co-owner of all of the company’s 21 issued US patents and 14 pending US patent applications.
GI said it had sought intellectual property protection outside the US and had been issued 28 patents in Australia, Europe and Japan and had 21 pending international applications.
GI said Gore claimed the supply agreement for the liner material was void, removing Gore’s obligation to supply GI the material necessary for the manufacture of its products.
GI said it was “vigorously defending all of the claims made by Gore and is pursuing counterclaims against Gore”.
GI said that should Gore be partially or wholly successful in its claims, Gore could become the co-owner of some or all of the company’s patents and may terminate the supply of liner material and “such an outcome may have implications for the conduct of the company’s business”.
The company’s website said major investors included Johnson & Johnson Development Corp, ATV Associates, Polaris, Domain Assoc, Cutlass Capital and Medtronic.
The offer opened on August 11, and closes on August 26, 2011.

SIRTEX MEDICAL

Sirtex founder and former chairman Dr Bruce Gray has reduced his substantial holding from 11,179,369 shares (20.05%) to 9,665,047 shares (17.33%).
Dr Gray sold the shares through his company ACN 132 442 114 Pty Ltd.
Dr Gray and Sirtex were previously involved in a protracted legal dispute with the University of Western Australia over the ownership of the Sir-Sphere intellectual property and Dr Gray has voted his significant shareholding against Sirtex resolutions to meetings.
Sirtex was unchanged at $5.37.

CLOVER CORP, CSIRO

Clover Corp says it will develop encapsulation technology for infant formula and medical food applications with the Commonwealth Scientific and Industrial Research Organisation.
Clover said the $1.2 million targeted three-year research program was part of the CSIRO Australian Growth Partnership Program and would use the intellectual property and expertise of both Clover and the CSIRO.
The company said the agreement built on more than 15 years of collaboration with the CSIRO on the development and commercialisation of functional ingredients.
Clover said the nutritional importance of docosahexaenoic acid (DHA) and other essential dietary fatty acids was “reflected in the strong market demand for their inclusion in functional and stable ingredients that can be used in applications such as infant formula, medical foods and pharmaceuticals”.
The company said the continuing challenge was how to stabilize the fragile nutritional bioactives, alone or in combination, so they could be used in the applications required by consumers and manufacturers.
Clover said the research program with the CSIRO would investigate how nutritional bioactives could be combined in formulas with the essential omega-3 fatty acid (DHA) to improve their stability in processing and to enhance their nutritional impact.
The company said that encapsulation matrices would be developed that could protect the bioactives during product manufacture, influence their absorption or bioactivity and to assist their physiological performance.
Clover was up 2.5 cents or 8.8 percent to 31 cents.

HELICON GROUP

Helicon says it has completed its due diligence and finalized the transaction to acquire the intellectual property associated with Ozpharma’s buccal Linguet tablet technology,
Helicon said it would pay Ozpharma of $50,000 and 1,370,000 shares for the technology which increased drug load capacity while reducing side effects commonly associated with other means of drug absorption (BD: June 29, 2011).
Helicon was up 0.6 cents or 30 percent to 2.6 cents.