Biotech Daily

Monday August 17, 2009

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: BENITEC UP 14%, TISSUE THERAPIES DOWN 10%**

*** FDA CLEARS MESOBLAST PHASE II LUMBAR SPINE FUSION TRIAL**

*** MESOBLAST REQUESTS ANGIOBLAST 'CAPITAL RAISING' HALT**

*** CHINA GREEN LIGHT FOR AVITA'S RECELL; HELICON DISTRIBUTOR**

*** PATRYS UNDERWRITER PNK TAKES MOST OF $5m SHARE PLAN**

*** LIVING CELL MEETING TO RATIFY 25.5m SHARES, 10.2m OPTIONS**

*** ANTISENSE ATL1101 SUPPRESSES RESISTANT PROSTATE TUMORS**

*** PHARMAUST FACTORY SELLING FOR $2.7m; 'WILL BE DEBT-FREE'**

MARKET REPORT

The Australian stock market was down 1.63 percent on Monday August 17, 2009 with the S&P ASX 200 falling 72.55 points to 4388.4 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 12 fell, 10 traded unchanged and five were untraded.

Benitec was best, up 0.4 cents or 13.8 percent to 3.3 cents with 390,166 shares traded, followed by Antisense up 0.3 cents or 8.1 percent to four cents.

Optiscan and Viralytics climbed more than seven percent; Impedimed was up 5.3 percent; Living Cell was up 3.2 percent; Circadian, CSL, Heartware, Mesoblast, Nanosonics and Resmed rose more than one percent; with Acrux, Cellestis and Novogen up by less than one percent.

Tissue Therapies led the falls, down 2.5 cents or 10 percent to 22.5 cents with 398,000 shares traded, followed by Sunshine Heart down 7.1 percent to 6.5 cents with 1.8 million shares traded.

Biota lost 5.8 percent with one million shares traded; Tyrian fell five percent; Clinuvel and Phosphagenics fell four percent or more; Alchemia, Pharmaxis and Progen were down more than three percent; Sirtex shed 2.1 percent; Chemgenex and Universal Biosensors were down more than one percent; with Cochlear down 0.23 percent.

MESOBLAST

Mesoblast says the US Food and Drug Administration has cleared a phase II clinical trial of its allogeneic adult stem cells in lumbar spinal fusion surgery.

Mesoblast said the 24-patient trial, based at multiple US sites, would compare the effectiveness and safety of two low doses of Mesoblast's off-the-shelf Neofuse product with an autograft from the patient's hip bone in minimally-invasive surgery for fusion of the lumbar spine.

The company said that more than 500,000 spinal fusion procedures were performed annually in the US alone.

Mesoblast said a minimally-invasive postero-lateral interbody approach was the preferred procedure by surgeons in about 80 percent of lumbar spinal fusions, with autograft remaining the FDA's gold standard, despite drawbacks such as graft pain and infection.

The company said that preclinical trials of Neofuse in minimally-invasive spinal fusion surgery in sheep showed that a lower dose than has previously been used in the lumbar spine resulted in significantly earlier bony fusion over three to six months compared with autograft, without any safety issues.

Mesoblast said that if these results were confirmed in the clinical trial, this would significantly reduce the cost of goods and increase product net revenues.

“Because of significant safety issues, competitor biologic technologies have not been able to gain FDA approval for use in this preferred type of minimally invasive lumbar fusion surgery,” Mesoblast said (BD: Aug 21, 2008).

The company said the minimally-invasive lumbar fusion trial would build on the safety and efficacy results generated in Mesoblast's first spinal fusion trial that employed a more invasive surgical approach.

Last year, Mesoblast reported “encouraging preliminary safety data from its ongoing phase II clinical trial” (BD: Apr 9, 2008) and hoped to begin a phase III trial in spinal fusion by mid-2009.

Today, Mesoblast said that in that trial, unilateral use of its Neofuse generated safe and robust fusion over a 12-month period.

Mesoblast’s executive director Prof Silviu Itescu told Biotech Daily that postero-lateral surgery had been superseded by more delicate and dangerous surgery entering directly into the interbody space between the vertebrae where the disc had been.

Prof Itescu said the new study would trial lower doses of Mesoblast’s adult stem cells in that interbody space.

In its media release the company said that if similar results were obtained in the minimally invasive trial, it would open a major commercial opportunity for Mesoblast.

After establishing safety and effectiveness during the conduct of this trial, Mesoblast plans to initiate a pivotal phase III trial to register its off-the-shelf product for the lucrative minimally-invasive lumbar spinal fusion surgery market.

MESOBLAST

Mesoblast has requested a trading halt pending an announcement regarding “a capital raising by our United States-based associate company Angioblast systems”.

Trading will resume on August 19, 2009 or on an earlier announcement.

Mesoblast last traded up two cents or 1.7 percent to $1.19.

AVITA MEDICAL, HELICON

Avita jumped as much as 143.5 percent to a high of 27.5 cents on news of Chinese regulatory approval for its Recell wound-care product.

Avita said the Chinese State Food and Drug Administration had issued “an unrestricted import licence” for Recell.

Avita chief executive officer Dr William Dolphin said that China was “a key market for the company’s products”.

Dr Dolphin said Recell could be used for cosmetic surgery, scar revision and burns treatment and was targeting “China’s burgeoning middle class, a rapidly growing segment of the country’s 1.3 billion people” as well as plastic and reconstructive surgeons, dermatologists, burns specialists and cosmetic specialists at high end military hospitals as well as larger private hospitals in major metropolitan centres of China.

Avita said Recell had strong sales potential in China where the cosmetics and plastics markets were growing exponentially and there were more than 100,000 cosmetic surgery clinics in China’s major hospitals.

The company said the annual market was about $US2.4 billion.

Avita said the Helicon Group would distribute Recell in China.

“Helicon has done an excellent job of shepherding the Recell application through the highly complex SFDA approval and registration process,” Dr Dolphin said.

Avita said it would train Helicon representatives and have meeting with key surgeons and influencers in the next few months.

The company has held meetings with key surgeons in China including highly placed surgeons in military hospitals, the company said.

Avita and Helicon will participate in conferences and workshops to maximize acceptance and uptake of Recell.

Avita closed up 8.5 cents or 73.9 percent at 20 cents with 7.1 million shares traded.

Helicon was up as much as 61.8 percent to 11 cents before closing up 0.7 cents or 10.3 percent to 7.5 cents with 2.8 million shares traded.

PATRYS

Patrys says its rights issue and share top-up plans have raised $5,036,686 from the issue of 20,146,746 shares at 25 cents a share.

Patrys had hoped to raise up to $6.8 million when it announced the one-for-six share plan and top up facility (BD: Jun 29, 2009).

The company said at that time the rights issue was underwritten by PNK Holdings to $5 million and that PNK was associated with Patrys director Michael Stork .

The company said right issue subscriptions were received for 4,531,829 shares with 2,418 shares subscribed in the top-up plan. PNK will take up the 15,612,499 shortfall shares.

Patrys fell 0.4 cents or four percent to 9.6 cents.

LIVING CELL TECHNOLOGIES

Living Cell shareholders will vote on one resolution to ratify the issue of 25,500,000 shares and 10,200,000 attaching options under ASX Listing Rule 7.4.

Living Cell said the shares were to be issued at 16.5 cents each and the options could be exercised at 24 cents each, by December 31, 2010.

The meeting will be held on September 17, 2009 at O’Loughlins Lawyers, Level 2, 99 Frome Street, Adelaide, at 12pm.

Living Cell was up half a cent or 3.2 percent to 16 cents.

ANTISENSE THERAPEUTICS

Antisense says in vitro data shows that ATL1101 suppresses tumor growth in drug-resistant prostate cancer cells.

Antisense said that “even in prostate cancer cells that were resistant to the growth suppressive effects of the taxane chemotherapy drug paclitaxel, ATL1101 treatment was still able to suppress tumor cell growth”.

The resistant cancer cells’ sensitivity to paclitaxel was also enhanced after ATL1101 treatment, the company said.

Antisense said the data from its ATL 1101 preclinical research project added to the “already comprehensive preclinical data set”.

The company said ATL1101 was a second-generation antisense drug to the insulin-like growth factor-I receptor (IGF-IR), a high-interest therapeutic target in oncology.

In October 2008, the company announced that ATL1101 treatment suppressed the growth of prostate tumors in mouse models of prostate cancer (BD: Oct 15, 2008).

Antisense said the latest in vitro data from collaborators at the Vancouver Prostate Centre added to the previously reported data supporting the therapeutic potential of ATL1101 in combination with taxane drugs.

The company previously reported that ATL1101 enhanced the tumor-suppressive effects of taxane anti-cancer drug paclitaxel, marketed as Taxol, when tumor-bearing mice were dosed with ATL1101 in combination with paclitaxel (BD: Jun 18, 2009).

Antisense said that resistance to the cytotoxic effects of taxane drugs was “a major issue in the management of castrate-resistant prostate cancer and other cancers”.

Paclitaxel and docetaxel, marketed as Taxotere, were taxane drugs with very closely related cellular mechanisms of action, the company said.

Antisense said both were prescribed to treat a range of cancers.

The company said Taxotere was approved as a prostate cancer treatment and Taxol, while not approved in that indication, has been used in the treatment of prostate cancer and was commonly used in studies investigating taxane pharmacology.

Taxol is approved for the treatment of other cancers including breast cancer.

Antisense said it was “in consultation with various parties regarding the continued development of ATL1101 in prostate cancer, aiming to build on ATL1101’s robust preclinical pharmacology data package, completed mouse toxicology study, established drug manufacturing process and strong intellectual property protection”.

Antisense said it would present a poster entitled ‘Targeting IGF-IR with antisense oligonucleotides in prostate cancer’ at the National Prostate Cancer Symposium at the Melbourne Cricket Ground on August 19-20, 2009.

Antisense was up 0.3 cents or 8.1 percent to four cents.

PHARMAUST

Pharmaust says it has an offer and acceptance contract for the sale of its property at 71 Division Street Welshpool near Perth in Western Australia for $2,700,000.

Pharmaust said the offer was conditional on the purchaser obtaining finance within 30 days and settlement within 30 days after that date.

Pharmaust said it would repay the mortgage against the property, and would be debt free.

Pharmaust was up 1.5 cents or 50 percent to 4.5 cents with 1.1 million shares traded.