Biotech Daily

Friday May 8, 2015

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: ATCOR UP 9%, NEUREN DOWN 5%**

*** CHIESI ADDS EU TO PHARMAXIS BRONCHITOL DISTRIBUTION**

*** POLYNOVO READY FOR NOVOSORB CE MARK DEEP BURNS TRIAL**

*** NOVOGEN: 'TRXE-009 KILLS DIPG BRAIN CANCER CELLS IN-VITRO'**

*** BONE REQUESTS 'ACQUISITION' TRADING HALT**

*** MEDICAL DEVELOPMENTS GLOBAL PENTHROX PLANS**

*** MARTIN ROGERS, DR JASON LOVERIDGE DILUTED IN ACTINOGEN**

MARKET REPORT

The Australian stock market slipped 0.2 percent on Friday May 8, 2015 with the S&P ASX 200 down 11.1 points to 5,634.6 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 11 fell, 11 traded unchanged and three were untraded.

Atcor was the best, up two cents or 9.3 percent to 23.5 cents with 208,333 shares traded.

Psivida climbed 7.45 percent; Pharmaxis was up 6.1 percent; Actinogen rose 5.7 percent; Biotron and Medical Developments improved more than four percent; Nanosonics, Prana and Starpharma were up more than three percent; Admedus, Bionomics and Optiscan rose more than two percent; with Anteo, Avita, Resmed, Sirtex and Universal Biosensors up more than one percent.

Neuren led the falls, down half a cent or 5.3 percent to nine cents with 3.2 million shares traded.

Clinuvel, Compumedics and Oncosil fell more than four percent; Benitec, Living Cell and Tissue Therapies lost more than three percent; Acrux, Impedimed and Viralytics shed more than one percent; with Cochlear, CSL and Mesoblast down less than one percent.

PHARMAXIS

Pharmaxis says that Chiesi Farmaceutici SpA will distribute Bronchitol for cystic fibrosis in Germany, the UK and Ireland, as well as the US, pending US approval.

Pharmaxis said that under the exclusive distribution and supply agreement, the Parma, Italy-based Chiesi would be responsible for the marketing, sales and distribution of Bronchitol (mannitol) for cystic fibrosis in adults aged 18 years and above in those markets from June 2015.

Last year, Pharmaxis ended its Novaquest dispute, saying that Chiesi would fund up to $US22 million of a pivotal trial of Bronchitol for cystic fibrosis (BD: Aug 4, Dec 24, 2014).

Pharmaxis said at that time that the distribution agreement with Chiesi for Bronchitol in the US followed the settling of the Novaquest dispute, the first patient had been enrolled in the phase III Bronchitol trial and subject to approval, Bronchitol would be sold as part of Chiesi's cystic fibrosis portfolio, with milestones of up to $US25 million payable tied to the launch of Bronchitol, and on achieving certain annual sales levels.

Today, the company said that Bronchitol was launched in Germany in 2012, in the UK in 2013 and was planned to be launched in Ireland after the assessment for reimbursement was concluded.

Pharmaxis company said it would manufacture Bronchitol for Chiesi but if it was independently sourced, Chiesi would pay an ongoing share of sales revenue.

Pharmaxis chief executive officer Gary Phillips said the company was "extremely pleased to have Chiesi as a distributor in these key European countries as well as in the United States, where an agreement was signed in December 2014".

"Chiesi's appointment also enables Pharmaxis to close its European commercial infrastructure and end its commercialization contract with Quintiles," Mr Phillips said.

"Distributors for other Western [European Union] countries such as Italy and Spain will be brought-on in-line with pricing and reimbursement approvals," Mr Phillips said.

Pharmaxis was up one cent or 6.1 percent to 17.5 cents with 5.2 million shares traded.

POLYNOVO

Polynovo says it expects to recruit the first of 20 patients in a Conformité Européenne (CE) mark directed trial of Novosorb for deep burns injuries by July 2015.

Polynovo said that the multicentre, randomized trial of Novosorb biodegradable temporizing matrix(BTM) had French regulatory and the Toulon Hospital ethics approvals.

The company said that the primary objective was to evaluate the safety and performance of Novasorb for the treatment of deep burns involving 20 to 50 percent of patients total body surface area and the the primary performance endpoint would be the "BTM take assessed by a histological analysis of the samples obtained by a centrally-located 4mm punch biopsy, at 28 days plus or minus two days after BTM placement".

Polynovo said that the primary safety endpoint was the incidence of invasive infection at BTM-treated lesions, as well as a raft of specified secondary performance endpoints.

The company said that Toulon Hospital was one of three sites with further centres awaiting ethics approvals and the trial was expected to take two years to complete.

Polynovo chief executive officer Paul Brennan said the trial was "a significant step towards meeting our regulatory strategies and requirements".

"With a CE mark Polynovo will be free to sell into a significant number of markets in Europe, and Asia Pacific," Mr Brennan said.

"The results we have seen to date in three patients in Adelaide have been outstanding," Mr Brennan said.

Polynovo was untraded at eight cents.

NOVOGEN

Novogen says an in-vitro study has shown that its TRXE-009 kills diffuse intrinsic pontine glioma cells and could be a therapy for the incurable paediatric brain cancer.

Novogen said that the data was presented by the University of New South Wales Children's Cancer Institute's Dr David Ziegler and Dr Anne Kankean at the Pediatric Neuro-Oncology Basic and Translational Research conference in San Diego, California held on May 7 and 8, 2015.

The company said that diffuse intrinsic pontine glioma (DIPG) had a median survival of less than one year and was among the most challenging cancers to treat.

Novogen said that the diffuse nature of the cancer meant that surgery was not an option, radiation provided only temporary relief and chemotherapy was yet to provide any clinical benefit.

The company said that the study looked at the ability of TRXE-009 to kill freshly established patient-derived cell cultures collected from patients with DIPG and indicated that TRXE-009 killed DIPG cells at therapeutically relevant concentrations by inducing caspase-dependent apoptosis, or cell death.

Novogen said that in contrast to its pronounced effect on DIPG cancer cells, normal brain astrocytes were affected only at much higher concentrations of TRXE-009, confirming data seen with other cancer cell types that TRXE-009 had a high therapeutic index and was able to target cancer cells at concentrations that had little effect on normal cells.

Dr Ziegler said the studies were preliminary "but we are very excited about the striking activity we are seeing in these highly resistant tumorspheres".

"TRXE-009 is one of the most potent compounds we have studied to date in this setting," Dr Ziegler said.

Novogen Trilexium program manager Dr Eleanor Ager said the findings "add to our other pre-clinical studies suggesting that TRXE-009 has particular activity against brain cancers, including being highly cytotoxic against the main adult brain cancer, glioblastoma multiforme".

"The next step in this drug's development is to confirm its ability to cross the blood-brain barrier, a key filtering system that blocks the majority of chemotherapeutic drugs from reaching brain tissue," Dr Ager said.

Novogen chief executive officer Dr Graham Kelly said that DIPG was "a devastating disease for affected children and their parents alike".

"I don't want parents to think that this battle is won, because we have yet to make sure we can deliver this drug candidate at levels that that will make a difference," Dr Kelly said.

"But what is important is to give parents of children with DIPG hope, and that is what this news hopefully does," Dr Kelly said.

Novogen was up four cents or 13.1 percent to 34.5 cents with 22.3 million shares traded.

BONE MEDICAL

Bone has requested a trading halt pending "a material announcement in relation to a business acquisition in the coming days".

Trading will resume on May 12, 2015 or on an earlier announcement.

Bone last traded down 0.1 cents or 10 percent to 0.9 cents.

MEDICAL DEVELOPMENTS

Medical Developments says that with its expected European Union approval for the Penthrox inhaled analgesic it is working to gain approval and sales globally.
Earlier this week, Medical Developments said that the UK Medicine and Healthcare Products Regulatory Agency, supported by France, Belgium and Ireland, has assessed the Penthrox methoxyflurane inhaled analgesic as approvable and the process moved to the "purely administrative" national phase which should take 30 days before marketing authorization was issued and Penthrox would be available for sale (BD: May 6, 2015).
Today, Medical Developments said that the approval "validates our regulatory dossier and the clinical and safety data we have obtained for Penthrox".
"It proves Penthrox is a world class product which regulatory authorities around the world can approve for sale," a Medical Developments media release said.
The company said it planned "to aggressively expand the number of countries which can sell Penthrox".
Medical Developments said that it would use the mutual recognition process to apply to other European Union countries to approve Penthrox, a process that usually takes about seven months.
The company said that the next approvals would focus on the largest markets in Europe including Germany, Italy and Spain and the UK regulatory dossier had been submitted or was in the process of being submitted to regulatory agencies in Russia, Saudi Arabia, Israel, Singapore, Hong Kong, Malaysia, Mexico, Taiwan and Iran, with approvals expected in the next 12 months.
Medical Developments said it was "focused on getting Penthrox approved for sale [in the US] as soon as possible".
The company said that its initial advice was that the regulatory dossier could be used as the basis for our submission to the US Food and Drug Administration, but another phase III clinical trial may be required to cover, among other things, the FDA's ethnic patient enrolment requirements for Hispanic, Asian and African Americans.
Medical Developments said it was "in the process of confirming our regulatory strategy with the FDA".
Medical Developments was up 11 cents or 4.5 percent to $2.56.

ACTINOGEN MEDICAL

Actinogen chairman Martin Rogers says his 36,250,000 shareholding in the company has been diluted from 7.55 percent to 6.07 percent in the recent capital raising.
Actinogen director and Corticrine founder Dr Jason Loveridge said that his holding with Warambi SARL of 27,717,184 shares had been diluted from 5.77 percent to below the five percent substantial level (BD: Dec 8, 2014).
Last month, Actinogen raised $10 million at 9.5 cents a share, with a share plan for a further $1.0 million due to close on May 14, 2015 (BD: Apr 24, 2015).
Actinogen was up half a cent or 5.7 percent to 9.3 cents with 2.6 million shares traded.