Biotech Daily

Wednesday March 6, 2013

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: ALCHEMIA UP 8%, ANTISENSE DOWN 8%**

*** MESOBLAST RAISES $170m FOR SPINE TRIAL, INFLAMMATORY DISEASE**

*** ALLIED CLAIMS 4 YEARS WITHOUT CALCIFICATION FOR CARDIOCEL**

*** COGSTATE, MERCK LAUNCH COGNIGRAM IN CANADA**

*** US PATENT FOR ALCHEMIA HYACT PLATFORM**

*** GI DYNAMICS SIGNS CMS AS BRAZIL DISTRIBUTOR**

*** PRANA PBT434 TARGETS PARKINSON'S ALPHA-SYNUCLEIN PROTEIN**

*** NOVOGEN, INGHAM COMBINE FOR SUPER-BENZOPYRANS FOR CANCER**

MARKET REPORT

The Australian stock market climbed 0.82 percent on Wednesday March 6, 2013 with the S&P ASX 200 up 41.4 points to 5,116.8 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 15 fell, nine traded unchanged and three were untraded. All three Big Caps were up.

Alchemia was the best, up 2.5 cents or 7.8 percent to 34.5 cents, with 332,805 shares traded, followed by Allied up 6.7 percent to 3.2 cents with 1.8 million shares traded.

Clinuvel climbed five percent; Prima and QRX were up more than four percent; Pharmaxis and Phosphagenics were up three percent or more; Acrux, Anteo, GI Dynamics, Resmed Sirtex and Starpharma were up more than one percent; with Cochlear, CSL and Mesoblast up by less than one percent.

Antisense led the falls, down 0.1 cents or 8.3 percent to 1.1 cents with 2.5 million shares traded, followed by Impedimed down 8.2 percent to nine cents with 287,206 shares traded.

Benitec, Circadian and Patrys lost more than seven percent; Ellex fell 4.35 percent; Avita, Bionomics, Genetic Technologies, Reva and Viralytics were down more than three percent; both Cellmid and Neuren shed 2.7 percent; with Medical Developments down 1.5 percent and Heartware down 0.8 percent.

MESOBLAST

Mesoblast says it will raise up to $170 million through the placement of shares at $6.30 each, taking its cash reserves to $332 million.
Mesoblast said the funds would be used to advance its mesenchymal precursor stem cell programs including lumbar spine and inflammatory disease.
The company said the placement to new and existing institutional investors was at a 2.2 percent discount, with shares to be issued and funds received about March 13, 2013.
Mesoblast said the funds would go to a phase III clinical trial of its mesenchymal precursor cells (MPCs) for degenerative disease of the lumbar spine.
In January, Mesoblast said a 24-patient phase II trial of its MPCs for lumbar spinal fusion had success rates comparable to the gold standard of bone autograft (BD: Jan 20, 2013).
The company said at that time that the cells were well tolerated, there was no evidence of ectopic bone fusion, with significant improvements in low back pain scores and total disability index.
Mesoblast said the funds would cover phase II trials to broaden the indications for intravenous treatment of systemic inflammatory conditions, as well as the optimization of manufacturing processes and increased product inventory, staff and overheads.
Mesoblast chief executive Prof Silviu Itescu told Biotech Daily the inflammatory conditions included “rheumatoid arthritis, diabetic renal disease and lung disease, among others”.
In a media release Prof Itescu said that in addition to the programs “already partnered with Teva Pharmaceutical Industries … we can utilize the funds received to drive our independent programs to commercial outcomes”.
Teva chief executive officer Dr Jeremy Levin congratulated Mesoblast on the financing and said Teva was “a partner focused on supporting Mesoblast through our alliance”.
“In particular, we are working closely together to develop an important new treatment for cardiovascular diseases,” Dr Levin said.
Mesoblast said that the issue of shares was within its 15 percent placement capacity and shareholder approval was not required.
Biotech Daily understands that Bell Potter was a lead manager to the placement.
Mesoblast was up one cent or 0.2 percent to $6.45 with 640,216 shares traded.

ALLIED HEALTHCARE GROUP

Allied Health says that four years after implanting its Cardiocel cardiac patches in its phase II extension study the patches showed no calcification.
Allied said that patients were assessed four years after congenital heart defects were repaired using the Cardiocel Adapt-treated bovine tissue.
The company said 25 patients were in the extension study, with seven patients beyond four years and six patients with more than three years without calcification.
Allied said there was no sign of calcium build-up at the site of repair, a result also seen when the same patients were reviewed at three years post-surgery.
Allied managing director Lee Rodne said that four years without calcification “when typically it is seen within six months post-surgery with existing marketed products is a significant result for us”.
Allied said it was in the process of seeking Conformité Européenne (CE) mark approval for Cardiocel and the company expected to file a 510(k) marketing approval submission to the US Food and Drug Administration “in the near future”.
The company said that Cardiocel was being used at Brisbane’s Mater hospital under the Authorised Prescriber Scheme with other hospitals expected to gain similar access.
Allied was up 0.2 cents or 6.7 percent to 3.2 cents with 1.8 million shares traded.

COGSTATE

Cogstate says it will begin the commercial rollout of its Cognigram computerized tool for early cognitive impairment with partner Merck Canada Inc this week.
Cogstate said the first patients would be tested this week marking the first time that Cognigram would be used in medical practice, outside clinical trials.
The company said that Cognigram was available at eight testing centres in Canadian cities with full distribution expected by the end of 2013.
Cogstate said that Cognigram was "a sensitive and robust computerized tool that enables accurate detection of early cognitive impairment and the monitoring of cognitive changes" to help detect the early stages of cognitive decline associated with neurodegenerative disease, such as Alzheimer's disease.
The company said the test cost the patient $C125 per test session.
Cogstate said that Merck Canada had exclusive rights to market and promote Cognigram in Canada and was responsible for marketing and promoting Cognigram to physicians and providing information for patients.
Cogstate chief executive officer Brad O'Connor said the launch was "a momentous event for Cogstate and the first step in driving change in the way physicians manage testing the cognition of their patients, particularly when it comes to detecting the earliest signs of dementia and Alzhiemer's disease".
Mr O'Connor said that Canada was an important market and the company was "extremely pleased" with Merck's investment and with the early interest generated in Cognigram.
Cogstate was up three cents or 8.6 percent to 38 cents.

ALCHEMIA

Alchemia says it has been granted a US patent critical to its platform technology.
Alchemia said the patent, entiled 'Hyaluronan-Chemotherapeutic agent formulations for the treatment of colon cancer', was "a critical development milestone for the company and provides US protection for the use of the company's proprietary drug HA-irinotecan in the treatment of metastatic colorectal cancer".
The company said that HA-irinotecan was being evaluated in more than 400 patients in a pivotal phase III clinical trial at 76 sites globally.
Alchemia said that the patent protected the company's Hyact drug delivery platform for a range of other anti-cancer drugs that could be used for drug resistant colorectal cancer.
Alchemia's head of intellectual property and technology transfer Dr Mike West said the patent demonstrated the broad clinical and commercial capability of the Hyact platform.
"This patent fits neatly in a suite of granted patents in other jurisdictions including Australia, Canada, China, Japan, Taiwan and Europe and will greatly enhance Alchemia's efforts in commercializing HA-irinotecan," Dr West said.
Alchemia said that further US patent applications were pending and were expected "to further cement the company's monopoly rights over the entire platform technology".
The company said the patent provided protection until July 13, 2021 with 846 days of patent term adjustment.
Hyact inventor and Alchemia's chief scientific officer Dr Tracey Brown said the patent claims substantiated Hyact's clinical novelty and provided protection for several Hyact targeted drugs in one of the world's largest oncology markets.
"This patent substantially expands the commercial application of our proprietary Hyact technology and provides Alchemia with the commercial rationale to continue to develop its extensive pipeline of oncology drugs," Dr Brown said.
Alchemia was up 2.5 cents or 7.8 percent to 34.5 cents.

GI DYNAMICS

GI Dynamics says it has signed CMS Medical to distribute its Endobarrier for obesity and type 2 diabetes in Brazil.
GI Dynamics said that the Goiânia, Brazil-based CMS would be the exclusive distributor of Endobarrier in Brazil, following regulatory approval of the product in that country.
The company said it was working closely with Scitech Produtos Medicos, a sister company of CMS, to help manage the regulatory process.
GI Dynamics was up one cent or 1.3 percent to 78 cents.

PRANA BIOTECHNOLOGY

Prana says that PBT434 reduces the aggregation and accumulation of the key protein alpha-synuclein in multiple transgenic animal models of Parkinson's disease.
Prana said that the alpha-synuclein protein aggregated inside the nerve cells of the substantia nigra, the part of the brain that is progressively damaged in the disease responsible for controlling movement.
The company said that the alpha-synuclein protein aggregates were associated with the onset and progression of Parkinson's disease, and in three different animal models, PBT434 significantly prevented the death of substantia nigra brain cells.
Prana said that PBT434 would be presented at two conferences in March.
Prana's head of research Prof Robert Cherny said the data suggested that PBT434 intervened in metal dependent pathways which otherwise promoted the aggregation of alpha-synuclein and PBT434 prevented the death of substantia nigra cells.
"We have observed marked improvements in motor function and coordination with PBT434," Prof Cherny said.
Prana was unchanged at 22.5 cents.

NOVOGEN

Novogen says it has a memorandum of understanding with Sydney's Ingham Institute to develop super-benzopyran molecules as anti-cancer drugs.
Novogen said that to bring lead molecule CS-6 and related drugs to market it would establish a network of research groups, with the Ingham Institute the first participant.
In February, Novogen said that an in-vitro study of CS-6 had shown anti-cancer activity against cancer cells representative of malignancies, including ovarian cancer and glioma (BD: Feb 19, 2013).
Novogen said the Institute was a partnership between the South Western Sydney Local Health District, the University of Western Sydney, the University of New South Wales and Liverpool Hospital, with fundamental and translational cancer research a main activity.
Novogen chief executive officer Dr Graham Kelly said the US Food and Drug Administration "recent announcement of the availability of Breakthrough Therapeutic Designation for drugs such as CS-6, means that we need to work with groups that have the capacity to fast-track early-stage clinical testing".
Novogen fell 1.5 cents or 6.5 percent to 21.5 cents.