Biotech Daily

Monday March 24, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: IDT UP 20%, COCHLEAR DOWN 3%**

*** PATRYS PREPARES FOR PAT-LM1 LYMPHOMA TRIAL**

*** FDA SETS APRIL 22 FOR QRX HEARING**

*** DIMERIX RAISES $1.5m FOR DMX200 FOR PROTEINURIA**

*** ISRAEL ISSUES PATENT FOR IMUGENE'S HER-VAXX**

*** GENETIC TECHNOLOGIES, PROMEGA SETTLE**

*** COGSTATE TESTS TO BE USED IN A4 ALZHEIMER'S STUDY**

*** BLUECHIIP, MICRONIC CO-DEVELOPMENT AGREEMENT**

*** BONE, WILLIAM HARVEY WORK ON BN006 FOR RHEUMATOID ARTHRITIS**

*** MASS MUTUAL REDUCES, DILUTED TO 6% IN NOVOGEN**

*** BIO-MELBOURNE BREAKFASTS ON RNAi**

MARKET REPORT

The Australian stock market edged up 0.16 percent on Monday March 24, 2014 with the S&P ASX 200 up 8.8 points to 5,346.9 points. Thirteen of the Biotech Daily Top 40 stocks were up, eight fell, 14 were unchanged and five were untraded.

IDT was the best, up six cents or 20 percent to 36 cents with 19,500 shares traded, followed by both Patrys and Uscom up 10.9 percent to 5.1 cents and 25.5 cents, respectively, with 20.75 million shares and 79,264 shares traded, respectively, with Antisense up 10.3 percent to 21.5 cents with 3.1 million shares traded.

Benitec climbed 5.85 percent; Optiscan was up four percent; Cellmid was up 3.45 percent; Living Cell rose 2.6 percent; Compumedics, CSL, Ellex and Nanosonics were up more than one percent; with Acrux and Osprey up by less that one percent.

Cochlear led the falls, down $1.71 or 2.9 percent to $57.25 with 319,999 shares traded. Impedimed and Mesoblast shed more than two percent; Bionomics, Genetic Technologies, Neuren, Resmed, Tissue Therapies and Universal Biosensors were down more than one percent; with QRX down by less than one percent.

PATRYS

Patrys says that pre-clinical studies have shown PAT-LM1 efficacy with lymphoma cell lines and patient samples and manufacturing has begun for clinical trials.
Patrys said PAT-LM1 was the second immunoglobulin M (IgM) antibody in its pipeline, after PAT-SM6, to enter clinical development and would target relapsed and refractory lymphomas.
The company said that PAT-LM1 was a natural human antibody that had shown promise in pre-clinical development as a potential treatment for multiple types of cancer, including colon, lung, breast, ovary, pancreatic and various haematological cancers.
Patrys said that the most recent laboratory experiments focused on the evaluation of the efficacy of PAT-LM1 in blood cancers including different types of leukaemias and lymphomas and the compound “showed very strong and specific binding to more than 90 percent of tested lymphoma cell lines and patients samples”.
The company said that PAT-LM1 was able to induce cell death in mantle cell lymphoma and histio-cytic lymphoma cells.
Patrys said that PAT-LM1 also bound specifically and strongly to some rare lymphoma types such as marginal zone B-cell and Burkitt lymphoma, indicating that it might have broad therapeutic application covering the whole range of different lymphomas.
The company said there were “numerous drugs on the market for lymphoma, [but] there is still a significant unmet medical need especially in patients with relapsed and refractory disease”.
Patrys said that the prognosis for these patients was poor and the development of novel agents, such as PAT-LM1, was urgently needed.
The company said that the cell line development of PAT-LM1 for production had been completed and early data indicated that the resultant yield from a GMP manufacturing run was likely to be significantly higher than yields achieved to date.
Patrys said it had begun the manufacturing process to produce PAT-LM1 for a future clinical trial.
Patrys chief executive officer Dr Marie Roskrow said that the pre-clinical results confirmed the potential of PAT-LM1 as an effective therapy for a broad range of lymphomas.
“Currently we anticipate that this antibody will be moved into clinical trial at the University of Würzburg where we will be working with the same clinicians who successfully executed the recent PAT-SM6 multiple myeloma trial,” Dr Roskrow said.
Patrys was up half a cent or 10.9 percent to 5.1 cents with 20.75 million shares traded.

QRX PHARMA

QRX says that the US Food and Drug Administration has set April 22, 2014 for the advisory committee meeting to consider its resubmitted Moxduo new drug application.
QRX chief executive officer Dr John Holaday said the Prescription Drug User Fee Act date was May 25, 2014 and the company looked forward to presenting the Moxduo clinical data to the advisory committee, “highlighting what the company believes is Moxduo’s respiratory benefit from Study 022” (BD: Jun 27, 2012; Nov 26, 2013).
The company said that Moxduo was an immediate release dual opioid for moderate to severe acute pain, in a three-to-two ratio of morphine and oxycodone.
QRX said that the advisory committee meeting would be open to the public and will be held from 8am to 5pm at the FDA White Oak Conference Center in Silver Spring, Maryland and would be webcast live, with details to be provided by the FDA, with additional information at: http://www.fda.gov/AdvisoryCommittees/default.htm.
QRX fell half a cent or 0.6 percent to 86 cents.

DIMERIX BIOSCIENCE

Dimerix says it has completed the first close of its mezzanine round above its $1.5 million minimum to take DMX200 to phase II clinical studies for chronic kidney disease.
Dimerix said that the funding meant Dimerix was beginning the process to convert from a private company to a public unlisted company ahead of a planned initial public offer.
Dimerix executive director Dr James Williams said the company was “extremely pleased” to close the fundraising.
“Subsequent completion of an [initial public offer] will allow the company to advance DMX200 through the clinic as well as accelerating additional pre-clinical and clinical programs originating from Dimerix’s core technology platform”.
Dimerix said that the raising was supported by corporate adviser Peloton Capital with the company’s management, existing shareholders and close associates.
The company said it had completed pre-clinical studies for DMX200, demonstrating a reduction of proteinuria in chronic kidney disease.
Dimerix said it had contracts with two pharmaceutical companies to use its proprietary core platform technology, Receptor-HIT, which enabled interrogation and understanding of the signalling pathways triggered when drugs act at complexes of receptors, rather than receptors signalling in isolation.
Dimerix is a private company in transition to a public unlisted company.

IMUGENE

Imugene says that the Israeli Patent Office has issued an intention to grant a patent for its HER-Vaxx cancer vaccine to October 2027.
The Israel Patent Office said that the patent application was entitled ‘Vaccine against cancerous diseases associated with the HER-2/neu oncogene and its use for the preparation of medicament for sustaining its biological response in the treatment of cancerous diseases associated with the HER-2/neu oncogene’.
Imugene company said that HER-Vaxx was a proprietary therapeutic cancer vaccine that stimulated a polyclonal antibody response to HER-2/neu, the same biomarker targeted by the $US6.9 billion a year drug, Herceptin, which had completed a phase I study in breast cancer to be followed by a phase II study in gastric cancer.
Imugene executive director Dr Nick Ede said that the expansion of the patent portfolio in Israel was “a significant step in our commercialization strategy”.
“Not only does it demonstrate the strength of our novel vaccine technology, but it enables us to explore new burgeoning markets for licencing opportunities in the multi-billion dollar vaccine market,” Dr Ede said.
Imugene fell 0.1 cents or 6.7 percent to 1.4 cents with 1.1 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says it has a settlement, covenant and licence agreement with Madison, Wisconsin-based Promega Corp.
Genetic Technologies said the agreement granted broad rights to Promega in relation to the company’s Intron sequence analysis and genomic mapping patents.
The company said that the commercial terms of the agreement were covered by formal confidentiality provisions.
Genetic Technologies fell 0.1 cents or 1.7 percent to 5.8 cents.

COGSTATE

Cogstate says its cognition testing technology will be used to track the neurological health of elderly people in a phase III trial of Eli Lilly's Alzheimer's disease drug solanezumab.
Cogstate said that the 1,000-patient A4 trial would be run by the US Alzheimer's Disease Cooperative Study, a cooperative agreement between the National Institute on Aging and the University of California, San Diego and would assess solanezumab, which might prevent, or slow the onset, of dementia in those considered at-risk but yet to show Alzheimer's disease symptoms.
The company said that details of the trial were published in the journal Science Translational Medicine in an article entitled 'The A4 Study: Stopping AD Before Symptoms Begin?'
A brief abstract is at: http://stm.sciencemag.org/content/6/228/228fs13.abstract.
Cogstate said that its cognition tests, delivered using an Apple Ipad, assessed reaction times and visual memory through a series of playing card-based challenges.
Cogstate said the trial would involve people aged 65 to 85 years who were in the asymptomatic phase of Alzheimer's disease with elevated brain levels of amyloid, but were healthy and yet to show any outward signs of dementia.
The company said that participants in the study would undergo positron emission tomography brain scans to track brain amyloid levels, and would have their memory function and other cognitive abilities tested with Cogstate's computer-based tests at the start of the study and at seven separate intervals during the 48 month trial.
Cogstate said that trial participants would be randomized to solanezumab or a placebo, to assess whether the drug can slow or prevent onset of Alzheimer's disease.
The company said that success of the trials do not require amyloid as the cause of Alzheimer's disease, but that amyloid was one critical factor that could be targeted prior to widespread, irreversible neuro-degeneration.
Cogstate chief scientific officer Prof Paul Maruff said that the Cogstate test battery was sensitive to amyloid related cognitive decline.
"These same Cogstate tests have also been shown repeatedly to be sensitive to the effects of novel and licensed drugs that modify cognitive symptoms in early [Alzheimers' disease]," Prof Maruff said.
Cogstate was up 0.5 cents or 1.5 percent to 34.5 cents.

BLUECHIIP

Bluechiip says it has signed a co-development agreement with the Lelystad, Netherlands-based Micronic Manufacturing BV.
Bluechiip said this company was part of the same Micronic group as its North American distribution partner Micronic America.
The company said the co-development agreement is to develop a dual identity vial for the cryo-preservation market, incorporating both the Bluechiip RF micro-electro mechanical systems (Mems) identification tag and Micronic's 2D data-matrix code.
Bluechiip said that the two companies would collaborate in the selling and marketing of
Bluechiip acting chief executive officer Jason Chaffey said that the project "brings together two innovations in the field of sample management that has the potential to deliver the most advanced and secure [identification] and temperature tracking product for the growing bio-banking market".
Bluechiip was unchanged at 6.8 cents.

BONE MEDICAL

Bone says it has a research agreement with the London-based William Harvey Research to study its BN006 anti-inflammatory molecule for rheumatoid arthritis.
Bone said the research would support the progress of BN006 towards clinical studies.
Bone chief scientific officer Dr Roger New said that in previous experiments BN006 showed efficacy in a rheumatoid arthritis disease model that was similar to the current market-leading product but with reduced inhibition of an important immune system marker.
“This could represent the profile of a breakthrough new medicine for [rheumatoid arthritis] with potentially less risk of the immunosuppressive side effects that limit current treatments, and given orally rather than by injection,” Dr New said.
Bone said that the collaboration was funded by its recently completed recapitalization.
Bone was unchanged at 2.6 cents with 6.6 million shares traded.

NOVOGEN

Oppenheimer Funds entity Massachusetts Mutual says it has reduced its substantial holding in Novogen from 9,867,292 shares (6.908%) to 9,730,000 (5.773%).
The shareholding was diluted by a number of conversions of convertible notes since the last substantial shareholder notice (BD: Jul 4, Aug 30, 2013).
The substantial shareholder notice was filed by the Sydney office of law firm, DLA Piper, for the Massachusetts-based MM Asset Management.
Novogen fell one cent or 5.3 percent to 18 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says its April 8 Bio-Breakfast will discuss increased investor interest as well as commercial and technology advances for RNA interference technology.
Bio-Melbourne Network chief executive officer Michelle Gallaher said that several pharmaceutical companies exited this technology over the last few years largely due to the challenges in translating this technology into the clinic.
“However in recent times there have been a number of RNAi companies that have been hugely successful in raising capital, including Australian company Benitec, and there now seems to be a number of players in this area,” Ms Gallaher said.
The Network said that Benitec chief executive officer Dr Peter French would discuss the commercialization path of RNAi technology and why it was attracting serious investor interest.
The Network said that the Commonwealth Scientific and Industrial Research Organisation’s project leader Dr Thilak Gunatillake would present on the latest technologies to successfully deliver small interfering RNA (siRNA) and the versatility of this technology both in human health and agricultural biotechnology.
The Bio-Melbourne Network said that the Bio-Breakfast would be held at the CSIRO Clayton campus, Monash University, Bayview Road, Clayton.
Registration is from 7:15am followed by a buffet breakfast with presentations from 8am to 9am.
For more information and to register go to: http://www.biomelbourne.org/events/view/315.