Biotech Daily

Tuesday April 15, 2014

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: BIONOMICS UP 5%, BENITEC DOWN 19%**

*** NSW $65k GRANTS FOR SAN DIEGO BIO 2014 CLOSE IN 14 DAYS**

*** MEDICINES AUSTRALIA CALLS FOR FEDERAL RESEARCH 'CERTAINTY'**

*** BLUECHIIP TO SUPPLY TRACKING CRYOPIN TO SYNCHROTRON**

*** CELLMID, BIOTECNOL COLLABORATE ON MIDKINE TRIBODIES**

*** PSIVIDA, ALIMERA SEPTEMBER FDA ILUVIEN PDUFA DATE**

*** ROYAL ADELAIDE APPROVES PHARMAUST PPL-1 CANCER TRIAL**

*** BENITEC COMPLETES $31.5m PLACEMENT**

*** INNATE READY TO START MIS416 MS TRIAL IN JUNE**

*** BIONICHE SELLS ANIMAL HEALTH BUSINESS**

MARKET REPORT

The Australian stock market climbed 0.55 percent on Tuesday April 15, 2014 with the S&P ASX 200 up 29.3 points to 5,388.2 points. Eight of the Biotech Daily Top 40 stocks were up, 16 fell, 12 traded unchanged and four were untraded.

Bionomics was the best, up two cents or 4.6 percent to 45.5 cents with 61,312 shares traded.

Alchemia and Avita climbed four percent or more; Impedimed, Patrys, Resmed and Starpharma rose more than two percent; Mesoblast was up 1.5 percent; with Cochlear and Sirtex up by less than one percent.

Benitec led the falls, down 30.5 cents or 19.2 percent to $1.28 with 1.3 million shares traded, followed by IDT down 14.3 percent to 24 cents with 82,800 shares traded and Anteo down 11.1 percent to 16 cents with 19.5 million shares traded.

Antisense and Genetic Technologies lost more than nine percent; Reva fell 6.7 percent; Prana and Tissue Therapies fell more than five percent, Medical Developments fell 4.2 percent; Admedus, Neuren, Phosphagenics, QRX and Viralytics were down more than three percent; Acrux shed 1.5 percent; with CSL and Nanosonics down by less than one percent.

NEW SOUTH WALES GOVERNMENT

New South Wales Minister for Health and Medical Research Jillian Skinner said the State Government would invest $65,000 to sponsor the Australian pavilion at BIO 2014.

“We have several exhibition booths at the BIO 2014 International Convention and are offering financial support of up to $5000 to [New South Wales]-based health and medical research organizations,” Ms Skinner said.

A media release from Ms Skinner’s office said that the BIO 2014 convention would be held in San Diego, California from June 23 to June 26, 2014.

Ms Skinner said that the New South Wales Government invested more than $200 million a year in medical research and “leads the nation in medical device development, with almost half of all medical device firms based in NSW”.

“A NSW presence at the trade show will greatly improve our State’s standing in the national and international health and medical research sector,” Ms Skinner said, inviting companies, medical research institutes, universities, public sector research organizations and researchers who wanted to showcase their work at BIO 2014 to apply for funding.

Details on how to apply is at: http://www.health.nsw.gov.au/ohmr/Pages/bio2014.aspx.

Applications close on April 29, 2014.

MEDICINES AUSTRALIA

Medicines Australia has called for predictability and certainty for Federal Government-funded medical research.

Medicines Australia chief executive Dr Brendan Shaw told Biotech Daily that his organization wanted “a whole of government approach that takes into account the importance of maintaining a stable and predictable business operating environment, ensuring a strong [intellectual property] system and an efficient and cost effective environment for clinical trials and having globally competitive incentives which enhance Australia’s attractiveness as a destination for global investment in high-tech pharmaceutical manufacturing and [research and development]”.

Dr Shaw said he wanted to emphasize “the link between public sector research and private innovation as well as the great need for predictability and certainty”.

“Medicines Australia is keen to work with the Government and other stakeholders to identify the best strategies for developing Australia’s medicines industry,” Dr Shaw said.

“We are not asking for direct funding but there are obviously various initiatives that have been successfully used here and overseas to generate significant investment by the global medicines industry,” Dr Shaw said.

Dr Shaw said that Medicines Australia had made a detailed submission to the Federal Government’s ‘Securing Australia’s Manufacturing Future’ review.

In a media release Dr Shaw called for a new and renewed focus on developing the Australian medicines industry.

The media release said that Dr Shaw told the opening of the Pharmaceutical Sciences World Congress in Melbourne on April 13, 2104 that Australia had “a rich heritage of medicines derived from our natural environment and medical research”.

“The challenge for us here in Australia and for the industry more globally is that we want to do much more of this in Australia,” Dr Shaw said.

“The community is interested, the Government is interested, the research community is interested and the industry is interested in taking the step to the next level of commercial partnership between science, research and commercialization,” Dr Shaw said.

“We want an environment that fosters more investment and more partnerships between the public researchers and private industry,” Dr Shaw said.

BLUECHIIP

Bluechiip expects to supply its cryopin tracking product for protein crystallography applications to its first customer, the Australian Synchrotron, in April 2014.
Bluechiip said the Synchrotron had assisted in the development of the technology since a trial in 2012.
The company said that Australian Synchrotron staff would use the cryopins and readers for wireless tracking of a cryopin's identification and temperature history.
Bluechiip said that the technology was expected to allow both rapid mounting and automated tracking of samples, which in turn would increase the efficiency of crystal screening and data collection.
The company said that the technology was well suited for use at a synchrotron beam-line due to the varied nature of sample storage from 30oC to minus 196oC, frosting, ionizing and non-ionizing radiation and mechanical wear and tear.
Bluechiip said that the Australian Synchrotron was an essential component in the development of many knowledge-intensive industries, including biotechnology and nanotechnology, as well as pharmaceuticals, mining and telecommunications.
Bluechiip acting chief executive officer Dr Jason Chaffey said that "without the early involvement of the Australian Synchrotron and access to the beamlines, the development of this product would have not been possible, this product is a world-first tracking solution for macromolecular crystallography and we are pleased that the Australian Synchrotron is its first customer".
Australian Synchrotron industry support scientist Dr Alan Riboldi-Tunnicliffe said that the introduction of the Bluechiip tracking technology "would lead to a higher degree of automation and therefore better outcomes for our researchers".
Bluechiip was up half a cent or 9.1 percent to six cents.

CELLMID

Cellmid says it has a collaboration agreement with Biotecnol for the development of midkine Tribodies, targeting midkine and oncogenic proteins.
Cellmid said that the Portugal-founded, Herfordshire, UK-based Biotecnol was a pioneer of multi-specific antibody engineering with a validated and proprietary technology platform.
Cellmid said that Biotecnol would develop and validate the midkine Tribodies and Cellmid would conduct pre-clinical efficacy studies, with the two companies sharing further development costs and jointly owning new multi-specific drugs.
The company said the collaboration was expected to result in one or more novel midkine Tribodies, targeting midkine as well as inhibiting other undisclosed oncogenic targets.
Cellmid said the collaboration added intellectual property in immuno-oncology to its pipeline, with immuno-oncology drugs expected to reach $US29 billion a year by 2025.
Biotecnol chief executive officer Dr Pedro de Noronha Pissarra said that immuno-oncology was "the re-engaging of the patient's immune response to kill cancer using antibodies [and was] revolutionizing cancer treatment [and] using [midkine] antibodies and multi-targeting oncogenic proteins including immune checkpoints with the Tribody design could become a breakthrough in the way of treating many solid tumors".
Cellmid chief executive officer Maria Halasz said that Biotecnol's platform had been validated and its manufacturability "makes it a stand out amongst multi-specific technologies".
"The collaboration ... allows us to join the gold rush for novel targets and immune checkpoint regulators with a leading player in antibody engineering," Ms Halasz said.
Cellmid was unchanged at 2.4 cents with 6.8 million shares traded.

PSIVIDA CORP

Psivida says the US Food and Drug has set September 26, 2014 as the Prescription Drug User Fee Act (PDUFA) date for a decision on Iluvien for diabetic macular oedema.
Psivida said the FDA date followed licencee Alimera Sciences resubmitting its new drug application with labeling changes, addressing concerns about the manufacturing facility and providing additional safety data (BD: Oct 21, Dec 19, 2013).
The company said that the FDA acknowledged the resubmission was received as a complete class 2 response to the FDA's October 2013 complete response letter.
Psivida said the resubmission responded to questions raised in the FDA's October 2013 letter and provided data from Iluvien patients and from physician experience with the applicator in the United Kingdom and Germany where Iluvien was commercially available.
Psivida was untraded at $4.00.

PHARMAUST

Pharmaust says it has approval from the Royal Adelaide Hospital's research ethics committee to begin a phase I/II trial of PPL-1 for cancer.
Pharmaust said the trial would recruit up to 15 patients with a variety of late stage cancers, potentially including lung, pancreas, oesophageal, gastric, colorectal, ovarian, breast, prostate, liver, sarcoma, lymphoma, and melanoma, who had failed standard-of-care and had been without treatment for at least two weeks.
The company said that the study would look at increasing doses of PPL-1 in cohorts of patients with each dose being administered daily for a period of 28 days.
Pharmaust said the study would measure the safety and pharmacokinetics of PPL-1 and determine changes in various cancer markers.
The company said that patient tumors would be biopsied where possible and also studied with the aid of a computed tomography-positron emission tomography scanner.
Pharmaust said that the evaluation of PPL-1 was being undertaken in late stage cancer patients under the supervision of principal investigator Prof Michael Brown.
The company said that recruitment would begin as soon as site specific assessments had been undertaken and governance approval received.
Pharmaust executive chairman Dr Roger Aston said that "as a first-in-man rising dose pharmacokinetic evaluation, our priority is to show safety".
Dr Aston said the company was grateful to and acknowledged the University of New South Wales and its commercialization arm Newsouth Innovations for the discovery and continued support of the work from Sydney's St George Hospital.
Pharmaust was up 0.2 cents or 20 percent to 1.2 cents with 22.2 million shares traded.

BENITEC BIOPHARMA

Benitec says it has completed its $31.5 million private placement at $1.07 a share to accelerate development of lead compound TT-034 for hepatitis C (BD: Feb 24, 28, 2014).
Benitec said shareholders voted overwhelmingly in favor of ratifying the first tranche and approving the second tranche of the private placement to institutional investors at an extraordinary general meeting on April 10, 2014.
The company said the funds would be used to advance other programs including lung cancer, age-related macular degeneration, and hepatitis B programs.
Benitec said the placement was managed by Maxim Group US and Lodge Corporate in Australia.
Benitec fell 30.5 cents or 19.2 percent to $1.28 with 1.3 million shares traded.

INNATE IMMUNOTHERAPEUTICS

Innate says it expects to enroll the first of up to 90 patients in a phase IIb trial of the MIS416 for secondary progressive multiple sclerosis in June 2014.

Innate said the trial was “on-track and on-budget” and chief executive officer Simon Wilkinson said that the Raleigh, North Carolina-based contract research organization INC Research had been appointed to assist with the trial.

Mr Wilkinson said INC Research’s Australian business unit, formerly Trident Clinical Trials, had extensive experience running neurology trials.

Innate said that patients in the double blinded study would be randomized with 60 patients receiving MIS416 and 30 patients receiving placebo.

The company said that at the end of the study, both groups could be offered continued access to MIS416 under an extension protocol.

Innate said that the study would focus on accessing the efficacy of MIS416 by using several clinical measures of neuromuscular function backed by patient reported outcomes of treatment effect.

The company said that secondary progressive multiple sclerosis affected walking and hand function as well as eye sight and cognition and these disabilities would be measured regularly during the trial, which would also gauge the success of MIS416 treatment by monitoring the patients’ activities of daily living and quality of life, which could be severely affected by the significant body pain and fatigue.

Mr Wilkinson said the phase II trial would study different ways to measure improvements that were meaningful to both the clinicians and patients which would “allow us to select the right measures and determine the correct number of patients to take into a subsequent phase III approval trial”.

Innate was unchanged at 21 cents.

BIONICHE LIFE SCIENCES

Bioniche says its shareholders have voted in favor of the sale of its animal health business to Vétoquinol SA.

Bioniche said that at a special meeting of shareholders 39.4 percent of the issued and outstanding shares were voted, with 97.4 percent voting in favor of the sale, which was expected to close on April 15, 2014.

In 2011, Bioniche raised $30 million at $1.50 a share to develop its Urocidin bladder cancer treatment and listed on the ASX, but the drug was handed back to the company by its partner Endo Pharmaceuticals, the company delisted from the ASX and was the subject of shareholder dissent (BD: Nov 30, 2010; Jan 20, 2011; Jan 28, 2014).

On the Toronto Stock Exchange last night Bioniche fell half a Canadian cent or 3.17 percent to 22.5 Canadian cents, 21.8 Australian cents.