Biotech Daily

Monday March 17, 2014

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: BENITEC UP 16%, PHARMAXIS DOWN 9%**

*** UK EARLY ACCESS TO MEDICINES SCHEME STARTS IN APRIL**

*** BIONOMICS BNC105 RENAL CELL CANCER TRIAL TRADING HALT**

*** BIO-21 CLUSTER EXPANDS TO BIOMEDICAL RESEARCH VICTORIA**

*** VICTORIA $250k VOUCHERS FOR SIENNA, BLAMEY & SAUNDERS, NPLEX**

*** VIRAX ACQUIRES PATHWAY FOR GGTI-2418, PAUL HOPPER DIRECTOR**

*** ONCOSIL ETHICS APPLICATION STARTS PANCREATIC CANCER TRIAL**

*** IMUGENE APPOINTS GROUND ZERO FOR HER-VAXX FDA APPLICATION**

*** INVION WITHDRAWS BANKRUPTCY IN EX-CBIO EXECUTIVES CASE**

*** PROGEN PLEADS 'AWARENESS' TO ASX 25% QUERY**

*** OBJ PLEADS SCHULTZ TO ASX 36% QUERY**

*** BENITEC APPOINTS PROF CRAIG LEWIS NSCLC CHIEF MEDICAL ADVISER**

*** RHINOMED LOSES DIRECTOR SIMON ISAACS AKA 'LORD READING'**

MARKET REPORT

The Australian stock market fell 0.22 percent on Monday March 17, 2014 with the S&P ASX 200 down 11.8 points to 5,317.6 points. Twelve of the Biotech Daily Top 40 stocks were up, 13 fell, eight were unchanged and seven were untraded.

Benitec was the best, up 26 cents or 16.35 percent to $1.85 with 1.1 million shares traded, followed by Anteo up 14.3 percent to 28 cents with 15.1 million shares traded. Prana climbed 8.7 percent; Circadian was up 7.5 percent; Atcor, Oncosil and Starpharma were up four percent or more; GI Dynamics and Psivida rose more than two percent; with Alchemia, Clinuvel and Osprey up more than one percent.

Pharmaxis led the falls, down one cent or 8.7 percent to 10.5 cents with 2.1 million shares traded. Tissue Therapies lost 5.4 percent; Acrux, Impedimed, Phosphagenics and Prima fell more than four percent; Admedus, Cellmid and Genetic Technologies were down more than three percent; Mesoblast, Neuren, QRX and Viralytics shed more than one percent; with Cochlear and CSL down by less than one percent.

THE UK MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

The Medicines and Healthcare Products Regulatory Agency says the British Government has approved the Early Access to Medicines Scheme.

A media release from the Medicines and Healthcare Products Regulatory Agency (MHRA) said the Scheme would give patients with life threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorization.

MHRA chief executive Dr Ian Hudson said the Early Access to Medicines Scheme would be launched in April 2014".

"The scheme is intended to enable patient access to medicines for treatment of life threatening or seriously debilitating conditions where there is an unmet need," Dr Hudson said. "This is a major new development in medicines policy in the UK."

"The scheme offers a way by which unlicenced medicines can be available to patients before approval of a licence to benefit public health," Dr Hudson said.

"It will also enable companies to gain additional knowledge and experience of these medicines in clinical use," Dr Hudson said,

In 2012, the US Food and Drug Administration introduced its Breakthrough Therapy program in (BD: Feb 13, May 31, 2013).

The MHRA said that under the Early Access to Medicines Scheme it would give a scientific opinion on a new medicine or indication that had demonstrated a positive risk/benefit balance.

The MHRA said that the Scheme was voluntary and the opinion from the MHRA did not replace the normal licencing procedures for medicines.

The MHRA said it was responsible for the scientific aspects of the scheme and the scientific opinion would be provided after a two-step evaluation process, with a promising innovative medicines (PIM) designation, followed by the early access to medicines scientific opinion.

The media release said that the promising innovative medicines designation would give an indication that a product may be eligible for the Early Access to Medicines Scheme based on early clinical data.

The MHRA said that PIM designation would be issued after an MHRA scientific meeting and could be given several years before the product was licenced.

The MHRA said that companies wanting to move to the second phase of the early access to medicines scientific opinion must hold a PIM designation and provide further relevant data on quality, safety and efficacy.

The media release said that the MHRA scientific opinion would describe the benefits and risks of the medicine, based on the information submitted by an applicant after sufficient data had been gathered from the patients who would benefit from the medicine.

The MHRA said that the opinion would support the prescriber and patient to make a decision on whether to use the medicine before its licence was approved.

BIONOMICS

Bionomics has requested a trading halt "pending an announcement ... of results from its phase II BNC105 renal cancer clinical trial".

Bionomics began the 134-patient renal cell carcinoma trial in 2010 and in 2011 discontinued a separate 60-patient trial of BNC105 for mesothelioma saying the renal cell carcinoma trial would continue and at that time expected to complete enrolment by the end of 2012 (BD: Jan 27, 2010; Aug 3, 2011)

Trading will resume on March 19, 2014 or on an earlier announcement.

Bionomics last traded at 74 cents.

BIO-21 CLUSTER, BIOMEDICAL RESEARCH VICTORIA

The Parkville-based Bio-21 Cluster will expand its activities to include Monash University and Clayton-based organizations and be renamed Biomedical Research Victoria.

A media release from the Minister for Technology Gordon Rich-Phillips said that the State Government would provide $167,000 to assist the transition.

Biomedical Research Victoria chief executive officer Prof Jan Tennent told Biotech Daily that the original Bio-21 Cluster was comprised of 21 member organizations and the expanded organization's role would be "to provide a mechanism for research organizations to work with Government to create the policies, infrastructure and supportive environment necessary to tackle the major health, medical and scientific problems".

Mr Rich-Phillips said the Bio-21 Cluster had successfully brought together the biomedical and health sciences research community within the Parkville Precinct.

"The new organization, Biomedical Research Victoria, will include Monash University, the major medical research institutes in the Clayton Precinct and other universities and research-active hospitals across Victoria," Mr Rich-Phillips said.

"Biomedical Research Victoria will create a Victorian biomedical research approach that is international in focus, more collaborative and efficient," Mr Rich-Phillips said.

"Such a statewide biomedical research cluster will improve linkages within Victoria's world class [research and development] base," Mr Rich-Phillips said.

"It will also provide an excellent opportunity to further capitalize on Victoria's competitive advantage in biomedical research, further lifting the state's reputation as the leading global research hub," Mr Rich-Phillips said.

Mr Rich-Phillips said that since 2000, Victoria had invested more than $1.8 billion in driving the development of the State as "a world-leading centre for life sciences".

"Medical research drives a life sciences industry in Victoria, which employs an estimated 10,000 people and recently generated annual sales in excess of $8 billion," Mr Rich-Phillips said.

Bio-21 Cluster chair Prof Ian Gust said that the new funding would provide opportunities for global collaboration.

VICTORIA GOVERNMENT

The Victoria Government says three biotechnology companies have been awarded Technology Implementation vouchers worth up to $250,000 each.

The Minister for Technology Gordon Rich-Phillips said the Government had awarded 115 vouchers under the $8 million program, helping companies improve products, processes and services and their ability to compete in local and international markets.

Mr Rich-Phillips said that Sienna Cancer Diagnostics, Blamey & Saunders Hearing and Nplex had been awarded the vouchers.

"Sienna Cancer Diagnostics will use its voucher to work with three groups, including the Peter MacCallum Cancer Centre, to develop better cancer tests and improve their use of specialized control slides," Mr Rich-Phillips said. "Blamey & Saunders Hearing will work on developing Ihearyou Everywhere, a new system which is changing the way people can adjust their hearing aids, with assistance from a blue tooth device ... and Nplex Pty Ltd from Bellbrae will work with Planet Innovation to develop low-cost and high-precision diagnostic tests for infectious diseases," Mr Rich-Phillips said.

Mr Rich-Phillips said the technology vouchers were designed to assist companies to navigate the early stages of demonstrating the technical viability of projects and scaling up for commercial implementation.

For more information about the program, go to: www.business.vic.gov.au/tvp.

VIRAX HOLDINGS

Virax says it will acquire Pathway Oncology, which holds a licence to GGTI-2418, a cancer drug that blocks the cancer growth enzyme geranyl-geranyl transferase I.

Virax said that GGTI-2418 was developed at the New Haven, Connecticut-based Yale University and the University of South Florida and invented by Florida's Moffitt Cancer Center director of drug discovery Prof Said Sebti and Yale's former provost and now Oxford University vice-chancellor Prof Andrew Hamilton.

In 2009 the Bonita Spring, Florida-based Tigris Pharmaceticals (now Kirax Corp) announced it would begin a US Food and Drug Administration approved phase I trial of GGTI-2418 for metastatic solid tumors, which it had licenced from Yale and the University of South Florida and in 2011, Tigris announced dosing its first patient, but no further information on that trial was available at the time of publication.

According to the Kirax website, the company "focuses on acquiring, developing and commercializing innovative specialty care therapies with emphasis on oncology, pain, inflammation, acute and supportive care" and has an opioid dose-pack as its lead product.

Virax said that GGTI-2418 blocked geranyl-geranyl transferase I (GGTase I) as well as Ral and Rho circuits in cancer cells, which are key oncogenic pathways for a cancer cell to survive and grow.

The company said that GGTI-2418 was a first-in-class synthetic peptidomimetic inhibitor of GGTase I, with the potential to treat multiple myeloma, breast and pancreatic cancers, and was a potent and selective drug that induced cell death by down-regulating several pivotal oncogenic and tumor survival pathways.

Virax said the drug had been shown to cause significant breast tumor regression in transgenic mouse models and had been demonstrated to be safe in a phase I trial at the University of Pennsylvania and Indiana University, where more than 30 percent of patients with advanced stage, treatment-refractory solid tumors demonstrated stable disease.

Virax said it would acquire Pathway with consideration of 60,000,000 shares on settlement, plus up to another 180,000,000 shares on achievement of milestones.

Virax chairman Dr Wayne Millen said that few ASX-listed biotechnology companies could claim "two advanced clinical programs to be conducted ... at two major US cancer institutions, impeccable scientific provenance with an extensive history of peer review and with GMP manufacturing established and clinical trial batch manufactured".

"This catapults Virax straight into an elite club of mid-clinical stage ASX-listed biotech companies," Dr Millen said

"We look forward to commencing the phase Ib/II trials and targeting patients whose tumors have disrupted signal circuitry, and therefore are most likely to respond to GGTI-2418, Dr Millen said.

Virax said that a phase Ib/II multiple myeloma study was planned at Moffitt Cancer Center, with Dr Melissa Alsina as the principal Investigator.

The company said that a phase II study with a nine-patient phase Ib lead-in, in combination with paclitaxel for women with P27 positive breast cancer was planned at Montefiore Einstein Center for Cancer Care in New York and the Moffit Cancer Center, with Dr Joseph Sparano as principal investigator.

Virax said that Paul Hopper would be appointed as an executive director.

The company said that Mr Hopper had more than 20 years experience in public company markets primarily in the life sciences sectors and was currently the head of life sciences at the Los Angeles-based Cappello Group, as well as executive chairman of Imugene and chairman of Viralytics.

Virax was up 0.2 cents or 13.3 percent to 1.7 cents with 9.6 million shares traded.

ONCOSIL MEDICAL

Oncosil says the submission of its application for ethics approval is the beginning of its pivotal clinical trial for its Oncosil localized radiation therapy for pancreatic cancer.
Oncosil said that the 150-patient trial at 20 sites had “the potential to be a global registration study [and was] a major milestone”.
The company said the randomized, controlled trial would compare patients receiving standard-of-care chemotherapy for inoperable pancreatic cancer with patients receiving standard-of-care plus Oncosil treatment, with 100 patients receiving Oncosil plus chemotherapy and 50 patients receiving chemotherapy alone.
Oncosil said that if positive, data generated by the trial might facilitate commercialization of Oncosil, which was classified as a class III medical device and not a drug.
The company said it planned to roll-out the trial in Australia, in parallel with trial sites in the UK, Belgium, Singapore and then the US.
Oncosil said it was finalizing preparations for its US Food and Drug Administration investigational device exemption (IDE) submission.
The company said that it expected the majority of patients would be enrolled within 12 months of the first patient and enrolment an interim analysis would be conducted at about 12 months from the date of commencement, when six months have elapsed since the first 30 patients entered the study.
Oncosil said that once enrolment was completed, it was expected to take 12-18 months to evaluate patients and determine their progress.
The company said that the key study measures would be overall survival, progression-free survival, quality of life and pain relief.
Oncosil was up half a cent or four percent to 13 cents with 4.2 million shares traded.

IMUGENE

Imugene says it has appointed Ground Zero Pharmaceuticals to manage its HER-Vaxx US Food and Drug Administration investigational new drug application.
Imugene said that Ground Zero specialized in supporting investigational new drug application submissions globally and particularly in the US.
The company said that HER-Vaxx was a 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.
Imugene said that HER-Vaxx had completed a phase I study in breast cancer and the next stage of development would be a phase II study in gastric cancer.
Imugene said that HER-Vaxx had shown success in stimulating the production of HER-2 antibodies in early-stage cancer patients enrolled in the initial clinical trial and its further development was directed to providing a natural, potentially more potent alternative to the injectable antibody Herceptin.
Imugene executive director Dr Nick Ede said that the filing and subsequent allowance of an FDA application would be “an important milestone”.
“A successful [application] can set the guidance for a key efficacy trial such as this and even reduce the time and risk involved in seeking FDA approval,” Dr Ede said.
“It may also allow for the inclusion of additional patients with other indications who may have a chance to benefit from the new drug,” Dr Ede said.
Imugene said the application included submission of manufacturing data, a protocol, investigator’s brochure, animal testing results, clinical safety and efficacy data and a clinical development plan, to permit the key new clinical study to be conducted.
Imugene was up 0.3 cents or 25 percent to 1.5 cents with 3.7 million shares traded.

INVION (FORMERLY CBIO)

Invion says it has withdrawn bankruptcy notices in legal proceedings against former officers of the company:
Invion said it reserved its rights to re-lodge the bankruptcy notices at a date subsequent to the Supreme Court trial, which was due to begin on May 5, 2014.
The company said it held the view that the defendants were required to pay about $67,000 for the costs of the interlocutory matters, pursuant to final orders received from the Supreme Court of Queensland and the Court of Appeal on February 17, 2014.
Last year, Invion said that one unnamed defendant in the legal action to recover about $1.2 million, agreed to repay his termination pay (BD: May 21, 2013).
Queensland Supreme Court documents named former executive chairman Stephen Jones, former chief executive officer Jason Yates, former chief financial officer James Greig and former company secretary Benjamin Graham as the defendants in the matter.
Invion was unchanged at 7.8 cents.

PROGEN PHARMACEUTICALS

Progen has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price climbed from 53 cents on March 13 to 66 cents, a 24.5 percent increase, on March 14, 2014 and noted an increase in trading volumes.
Progen said that existing shareholders and investors were "becoming increasingly aware of the advancement of the company's late stage drug PI-88 under development by licencee Medigen Biotechnology Corporation which is on track for new drug application filings in Asia" and could potentially be the first drug approved for the treatment of primary liver cancer following surgical resection.
The company said its most recent announcement was an update on December 30, 2013 saying Medigen had reached the target enrolment of 500 patients in its phase III trial.
Progen was up 24.5 cents or 37.7 percent to 89.5 cents.

OBJ

OBJ has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price rose 36.4 percent from 4.4 cents on March 10 to 6.0 cents on March 14, 2014, but did not note an increase in trading volume.
OBJ was up half a cent or 8.9 percent to 6.1 cents with 19.1 million shares traded.

BENITEC BIOPHARMA

Benitec says it has appointed Prof Craig Lewis as chief medical adviser on the company's non-small cell lung cancer (NSCLC) program.
Benitec said that Prof Lewis was a medical oncologist at Sydney's Prince of Wales Hospital, with an interest in clinical trial research in lung and breast cancer, sarcoma and cancer pain management, and would work for the company on a part-time basis.
The company said that Prof Lewis was a Fellow of the Royal Australasian College of Physicians, a member of the Medical Oncology Group of Australia, the American Society of Clinical Oncology and the Clinical Oncological Society of Australia and was an associate professor at the University of New South Wales' School of Medicine.
Benitec was up 26 cents or 16.35 percent to $1.85 with 1.1 million shares traded.

ACUVAX

Acuvax says that Dr Anton Uvarov has resigned as a non-executive director.
A healthcare analyst with RM Research, Dr Uvarov was appointed a director in October last year (BD: Oct 10, 2013).
Acuvax was untraded at 0.1 cents.

RHINOMED

Rhinomed says that director Simon Isaacs has resigned, effective from today.
Mr Isaacs was appointed a director in 2012 and according to Burke's Peerage is also known as the Marquess of Reading and was described by Consegna (formerly Helicon and now Rhinomed) as 'Lord Reading' (BD: Mar 1, 2012).
Rhinomed was up 0.3 cents or 8.8 percent to 3.7 cents with 1.7 million shares traded.