Biotech Daily

Thursday February 6, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PRIMA UP 9%, VIRALYTICS DOWN 7%**

*** APPROVALS FOR PRIMA PHASE II CVAC CANCER TRIAL CHANGES**

*** VIRALYTICS ISSUES FIRST $6m OF $27m RAISING**

*** MAYNE EXPECTS H1 REVENUE UP 159% TO $71m, LOSS TO PROFIT**

*** BLUECHIIP, ONQ INTEGRATE TRACKING, IT SYSTEMS**

*** LIVING CELL APPOINTS DR KEN TAYLOR NTCELL PROGRAM DIRECTOR**

MARKET REPORT

The Australian stock market recovered 1.21 percent on Thursday February 6, 2014 with the S&P ASX 200 up 61.1 points to 5,131.4 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 11 fell, 10 traded unchanged and four were untraded. All three Big Caps were up.

Prima was the best, up 0.4 cents or 8.9 percent to 4.9 cents with 22.8 million shares traded.

QRX climbed six percent; Acrux, Antisense, Bionomics, Clinuvel and Phosphagenics were up four percent or more; Optiscan, Tissue Therapies and Universal Biosensors were up more than three percent; Mesoblast and Patrys rose more than two percent; Cochlear was up 1.3 percent; with Alchemia, CSL, Medical Developments, Resmed and Sirtex up by less than one percent.

Viralytics led the falls, down 2.5 cents or 7.0 percent to 33 cents, with 363,176 shares traded.

Impedimed fell 4.55 percent; Admedus, Atcor, Neuren, Oncosil and Psivida lost three percent or more; Osprey shed 2.3 percent; Benitec and Nanosonics were down more than one percent; with GI Dynamics down 0.7 percent.

PRIMA BIOMED

Prima says regulators in Latvia, Lithuania, Bulgaria, Ukraine and Belarus have approved its amended protocol for its phase II trial of CVac for ovarian cancer (CAN-004).

Last year, Prima suspended its phase II/III CAN-004 Australian, European and US trial of CVac for ovarian cancer saying that that top-line analysis of its 63-patient CAN-003 phase II trial failed to show significant progression-free survival. (BD: Sep 19, Nov 7, 2013)

The company said at that time that it had suspended enrollment in the CAN-004 'Canvas' trial, which had been designed with progression-free survival as the primary endpoint, but currently enrolled patients could continue on the existing protocol.

The European arm of the 'Canvas' trial began in February 2013, following the US start in February 2012 (BD: Feb 3, 2012; Feb 5, 28, 2013).

Today, Prima described the trial as a phase II trial and said that overall survival would be the primary endpoint, with secondary endpoints including progression-free survival, adverse events and immune monitoring.

Prima said that the CAN-004 trial was approved by the Belgian regulators in January 2014 and the amended primary endpoint had been approved by ethics committees and institutional review boards in the US, Australia, Belgium, Bulgaria, Latvia and Lithuania.

Prima chief executive officer Matthew Lehman said the company was "pleased that the CAN-004 amendments have been promptly reviewed and approved by a number of regulatory agencies and ethics committees … [and] plans to start recruitment of the 210 ovarian cancer patients in second remission are on schedule".

Prima said that the CAN-004 multicentre, randomized, phase II trial of CVac for the maintenance treatment of epithelial ovarian cancer in remission would enrol 210 epithelial ovarian cancer patients in remission after second-line platinum-based chemotherapy.

The company said that 76 patients in remission after first-line surgery and chemotherapy were randomized onto part 1 of the CAN-004 trial.

Prima was up 0.4 cents or 8.9 percent to 4.9 cents with 22.8 million shares traded.

VIRALYTICS

Viralytics says it has raised the first tranche of $6.1 million in its $27 million placement and one-for-six non-renounceable rights issue at 28 cents a share.

In January, Viralytics said the placement had raised $23 million and it hoped to raise $4.1 million through the rights issue (BD: Jan 30, 2014).

Viralytics said in January that the proceeds would "fund the company to the end of 2016 including the completion of its key Cavatak clinical trials".

Today, Viralytics said that first tranche shares did not require shareholder approval.

Viralytics fell 2.5 cents or 7.0 percent to 33 cents.

MAYNE PHARMA

Mayne Pharma says it expects to post revenue for the six months to December 31, 2013 of $68.0 to $71.0 million with net profit after tax of $8.2 to $8.4 million

Last year, Mayne's revenue for the six months to December 31, 2012, was up 0.9 percent to $27,375,000, resulting in a loss after tax of $2,546,000 (BD: Feb 27, 2013).

Today, the company said it had $19.8 million in cash at December 31, 2013 and bank debt was $55.5 million up from $46.7 million at June 30, 2013.

The company said that the results were subject to auditor's review and were expected to be detailed on February 26, 2014.

Mayne was up 5.5 cents or 7.5 percent to 79 cents with 1.7 million shares traded.

BLUECHIIP

Bluechiip and Onq Software say they have completed the integration of their software products, Stream and QLIMS, respectively.

Bluechiip said the integration allowed Onq's QLIMS software to interface directly with Bluechiip storage sample readers to integrate Bluechiip sample chain-of-custody and temperature information with Onq Software's laboratory information management system, QLIMS.

Bluechiip said that QLIMS was extensively used in the pharmaceutical, mining, food, contract, water and waste water, semi-conductor, power stations, chemical and biological sciences industries.

The company said that the integration was a step towards establishing an effective chain of custody from delivery of the sample to its conclusion.

Bluechiip acting chief executive officer Dr Jason Chaffey said that QLIMS was "a powerful laboratory information management system that provides users with flexibility and analytical history, complementing our chain-of-custody software".

"This represents a significant milestone for Bluechiip, broadening the possible product applications to other areas of sample management," Dr Chaffey said.

Onq managing director Nick Gannoulis said the integration enabled "the potential of providing an end-to-end tracking … for chain of custody and temperature control".

Bluechiip was up half a cent or 9.3 percent to 5.9 cents.

LIVING CELL TECHNOLOGIES

Living Cell says it has appointed Dr Ken Taylor as NTCell program director to ensure the effective delivery of product development strategy and associated clinical trials.

Last year, Living Cell enrolled and implanted the first patient in a phase I/IIa clinical trial of NTCell for Parkinson's disease patient and the independent data safety monitoring board approved three more patients but the withdrawal of a published rat study halted phase the trial (BD: Sep 20, Nov 25, Dec 19, 2013).

Today, Living Cell said that Dr Taylor had completed a postdoctoral fellowship in pharmacology and experimental therapeutics at the Johns Hopkins University School of Medicine in Maryland and held a joint appointment in neurosciences at Princeton University and the Squibb Institute of Medical Research in Princeton, New Jersey.

The company said that Dr Taylor was previously Roche Australia's medical director, Roche New Zealand's managing director Roche UK managing director.

Living Cell said that Dr Taylor converted the Palo Alto, California-based Syntex pharmaceutical company into the Roche Bioscience Research Center.

The company said that Dr Taylor was previously chief executive officer of Antipodean Pharmaceuticals managing phase I and II studies of its lead compound in Parkinson's disease.

Living Cell said that Dr Taylor held degrees and a Doctorate of Philosophy in pharmaceutical chemistry and pharmacology from the University of Otago and completed a business management program in Lausanne, Switzerland.

Living Cell was unchanged at 7.8 cents.