Biotech Daily

Friday May 9, 2014

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: PRIMA UP 33%, COMPUMEDICS DOWN 9%**

*** BARDA TERMINATES $231m BIOTA CONTRACT**

*** WEHI: SOCS4 A KEY TO INFLUENZA RESPONSE**

*** US FAST TRACK STATUS FOR PRIMA'S CVAC FOR OVARIAN CANCER**

*** BLUECHIIP CHINA DEAL**

*** SUDA 40% EGM RESISTANCE, 2 RESOLUTIONS WITHDRAWN**

*** UNITED SUPER, CBUS TAKE 5% OF ACRUX**

*** POLARIS, DOMAIN REDUCES, DILUTED TO 4.6% OF GI DYNAMICS**

*** J&J REDUCES, DILUTED TO 6% OF GI DYNAMICS**

*** ATV, MEDTRONIC, GREENLIGHT DILUTED IN GI DYNAMICS**

*** UNILIFE APPOINTS JOHN RYAN GENERAL COUNSEL, CO SEC**

*** RHINOMED APPOINTS BADEN COOKE EUROPEAN BRAND AMBASSADOR**

MARKET REPORT

The Australian stock market fell 0.29 percent on Friday May 9, 2014 with the S&P ASX 200 down 16.0 points to 5,460.8 points. Thirteen of the Biotech Daily Top 40 stocks were up, 12 fell, 12 traded unchanged and three were untraded.

Prima was the best, up 1.2 cents or 33.3 percent to 4.8 cents with 84.7 million shares traded, followed by Oncosil up 14.9 percent to 10 cents with 8.8 million shares traded. Ellex climbed 8.3 percent; Prana was up 6.45 percent; Analytica, Biotron and GI Dynamics were up more than three percent; Optiscan rose 2.2 percent; Pharmaxis, Sirtex and Viralytics were up more than one percent; with Acrux, Cochlear, CSL and Nanosonics, up by less than one percent.

Compumedics led the falls, down one cent or 9.1 percent to 10 cents with 157,000 shares traded. Benitec lost 7.1 percent; both Circadian and Patrys fell 5.6 percent; Atcor fell four percent; Neuren, Phosphagenics and Tissue Therapies were down more than three percent; Genetic Technologies shed 2.4 percent; Alchemia, Mesoblast and Starpharma were down more than one percent; with Resmed down 0.4 percent.

BIOTA PHARMACEUTICALS

Biota says the US Biomedical Advanced Research and Development Authority has terminated its $US231 million contract to develop laninamivir octanoate (BD: Apr 1, 2011).

Biota says it received a notice from the US Department of Health and Human Services, the Office of Assistant Secretary for Preparedness and Response and Biomedical Advanced Research and Development Authority (BARDA), advising of the decision to terminate the contract.

Biota said the decision was the result of an in-process review and no reasons for the termination were provided to the company (BD: Apr 30, May 1, 2014).

BARDA director Dr Robin Robinson told Biotech Daily today that "with the challenges this development project encountered, we felt it was in the best interest of the taxpayer to support development of other promising influenza antiviral drugs already in our antiviral drug portfolio and possibly new drugs to treat critically ill patients with influenza".

"During a recent review, we shared our concerns with the company, including the number of people enrolled so far in Biota's phase II clinical trials to evaluate laninamivir in adults during the recent influenza season; the cost of additional clinical trials; emergence of resistance to laninamivir in recent H7N9 virus strains; and feasibility using of laninamivir to treat of critically ill, hospitalized patients with influenza," Dr Robinson said.

On April 30, Biota said it had not been given specific reasons for a 'stop-work order' but on May 1, Dr Robinson told Biotech Daily: "We have concerns about the project with regard to the product manufacturing, clinical study enrollment pace, costs, and contractor performance."

Biota later filed the same text to the US Securities and Exchange Commission.

Today, Biota said it intended to begin negotiating a final termination settlement with the Assistant Secretary for Preparedness and Response and BARDA.

The company said it was developing laninamivir octanoate, a long-acting neuraminidase inhibitor, administered by inhalation via the Twincaps dry powder inhaler, for the treatment of influenza A and B under an investigational new drug application in the US.

Biota said that as Inavir in Japan, laninamivir octanoate had been developed by partner Daiichi-Sankyo, where it was approved for the treatment and prevention of influenza A and B and since its 2010 launch, Inavir had become the leading antiviral to treat influenza.

The company said that since the 2011 start of the BARDA contract, it had completed three phase I trials, met the targeted enrolment in its phase II Igloo trial on time with top-line results expected by October 2014, begun enrolment in a phase I/II pediatric trial, improved the inhaler and made advances in process development and manufacturing.

Biota chief executive officer Russell Plumb said that "given the commercial success of Inavir in Japan over the past several years, the status of the program and with top-line data from the phase II Igloo trial anticipated in a matter of months, we are somewhat perplexed by this decision".

"We intend to complete the collection, analysis and reporting of the data from the Igloo trial, as well as the recently completed phase I trials," Mr Plumb said. "Subject to the results of Igloo trial, which we expect will be available in the third quarter, we will make a data-driven decision as to the next steps in the development of laninamivir octanoate."

In 2012, Biota merged with Maryland-based Nabi Pharmaceuticals saying that it was primarily for the BARDA contract and to access $US54 million in cash, eventually settling for $US27 million in cash (BD: Apr 23, Sep 18, Oct 30, 2012).

Biota later moved about 500 miles to Georgia despite claiming the proximity to the US Food and Drug Administration as one of the reasons for the merger (BD: Apr 17, 2013).

On the Nasdaq, Biota fell a further 20 US cents or 6.17 percent to $US3.04 ($A3.24) equivalent to 40.5 cents prior to the Nabi merger, when it was trading around $A1.00.

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

WEHI says that its researchers the SOCS4 protein slows the immune system's reaction to influenza infection, providing a possible means of minimizing the impact of pandemics.

The Institute said that its scientists found that without the suppressors of cytokine signalling 4 (SOCS4) protein, the immune response to influenza infection was slowed and there was a vast increase in the number of damaging inflammatory molecules in the lungs.

The Institute said that the flood of inflammatory molecules, known as a cytokine storm, was thought to contribute to influenza-related deaths in humans.

WEHI said that its staff Dr Lukasz Kedzierski, Dr Sandra Nicholson and colleagues, with the University of Melbourne's Prof Katherine Kedzierska made the discovery and published the study, entitled 'Suppressor of Cytokine Signaling 4 (SOCS4) Protects against Severe Cytokine Storm and Enhances Viral Clearance during Influenza Infection' in the US Public Library of Science Pathogens journal.

The article is available at: http://dx.plos.org/10.1371/journal.ppat.1004134.

WEHI said that suppressors of cytokine signaling molecules controlled the flow of chemical messages inside cells and were discovered by its researchers in the 1990s.

The Institute said that immune cells release signalling molecules called cytokines to trigger an immune response that protects the body from infection.

WEHI said that if too many cytokines were released, SOCS proteins suppressed the activity of the cytokines to prevent unwanted inflammation and tissue damage.

Dr Kedzierski said removing SOCS4 upset the normal immune response to influenza infection and his group showed that following influenza infection, the immune system did not respond as quickly as expected and initially sent key immune cells to the wrong location in the body.

"In addition, inflammatory cytokines began to accumulate in the lungs, leading to a cytokine storm that causes significant damage to the tissue," Dr Kedzierski said.

"A cytokine storm is like an uncontrolled chain reaction and the cytokines that normally stimulate the immune response continue to trigger other immune cells to produce more cytokines," Dr Kedzierski said.

"Our research suggests that SOCS4 keeps this response under control, preventing a cytokine storm in the lungs that can lead to a build up of fluid that restricts breathing and can ultimately result in death," Dr Kedzierski said.

WEHI said that cytokine storms were believed to be the primary cause of death in young and otherwise healthy people infected with influenza, particularly pandemic strains.

"Many of the estimated 50 million deaths caused by the 1918 flu epidemic are believed to have been caused by these cytokine storms," Dr Kedzierski said. "Cytokine storms in patients' lungs are also thought to be responsible for many of the 500,000 influenza-related deaths that occur around the world each year."

Dr Nicholson said that the role of SOCS4 in the body was previously unknown.

"When other SOCS proteins are removed from laboratory models, their function and the effect of their loss becomes immediately apparent," Dr Nicholson said. "However, the SOCS4-deficient model appeared to be completely normal."

"It was only when we looked at the response to infection that we found the immune system was significantly affected by the loss of SOCS4," Dr Nicholson said.

"Drugs that enhanced or mimicked SOCS4 action could be a useful way of treating pandemic or more aggressive 'flu strains, as well as other infections," Dr Nicholson said.

"Knowing the target and function of SOCS4 may lead to us being able to control inflammation in severe cases of the flu or to the development of new, preventive therapies," Dr Nicholson said.

PRIMA BIOMED

Prima says the US Food and Drug Administration has granted Fast Track designation for CVac for relapsed platinum-sensitive epithelial ovarian cancer in second remission.
Prima said it would work closely with the FDA in accelerating its CVac program.
Prima chief executive officer Matthew Lehman said that the designation was “an important milestone for Prima”.
“The FDA decision is in recognition of the serious nature of ovarian cancer and the clear unmet medical need to develop new treatments for relapsed platinum-sensitive ovarian cancer in remission,” Mr Lehman said.
“Building from our CAN-003 trial data, which indicated an improvement in progression-free survival in this patient population, we look forward to accelerating our recently commenced CAN-004-B trial to establish overall survival advantages of CVac as soon as possible,” Mr Lehman said.
Prima said that the Fast Track process was designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need.
The company said that Fast Track designation allowed for more frequent meetings with the FDA to discuss the drug’s development plan and ensure collection of appropriate data needed to support drug approval, more frequent written correspondence from FDA about the design of proposed trials and use of biomarkers, eligibility for accelerated approval and priority review and rolling review, meaning that a company can submit completed sections of its biological licence application or new drug application for FDA review, rather than waiting until every section of the application was completed before the entire application could be reviewed.
Prima said it was granted FDA Orphan Drug designation in September 2010 and in June 2010 by the European Medicines Agency.
Prima climbed 1.2 cents or 33.3 percent to 4.8 cents with 84.7 million shares traded.

BLUECHIIP

Bluechiip says it has a development and commercialization agreement with Macau’s Eastern Equipment Trading Company.
Bluechiip said the agreement included a licence to Eastern Equipment to market, distribute and sell Bluechiip products in China and to integrate Bluechiip’s tags into receptacles it would make and sell as integrated products.
The company said the agreement covering the Peoples’ Republic of China, Hong Kong and Macau had a term of seven years with an option to extend for a further three years and a 10 percent equity stake for Bluechiip in Chinanewco along with an upfront payment on signing, milestone payments and royalties
Bluechiip said the agreement included minimum orders which, including royalties receivable by Bluechiip, would provide about $500,000 in the first year with Bluechiip’s initial obligations $35,000 of product and technical sales assistance.
The company said that Eastern Equipment had begun registering Chinanewco in China as the nominee in the agreement, which would become the licensee.
Bluechiip said that Chinanewco’s major investor would be a private company based in Shanghai with interests in hospitals, technology and property in Asia Pacific.
The company said the agreement was the first deal reflecting its new commercialization strategy.
Bluechiip executive chairman Iain Kirkwood said the agreement was “a significant commercial breakthrough for Bluechiip”.
Bluechiip was up 1.3 cents or 31.7 percent to 5.4 cents.

SUDA

Suda faced strong resistance to an extraordinary general meeting to grant directors 32,500,000 options or the equivalent in performance rights and ratify prior share issues.
The strongest opposition was to the proposal to issue 10,000,000 options or 5,425,641 performance rights or a combination of options and performance rights to the equivalent maximum to chairman Michael Stewart, with 54,901,311 proxy votes (40.4%) against and 80,867,061 proxy votes (59.6%) in favor.
The proposal to issue chief executive officer Stephen Carter a maximum of 7,500,000 options or a maximum of 4,069,231 performance rights or a combination of options and performance rights to the equivalent maximum was opposed by 54.9 million votes and supported by 91.7 million votes.
Resolutions to issue the same quantities to chief financial officer Joseph Ohayon and director Ken Robson were withdrawn by the company.
Proposals to adopt the employee share option plan, employee performance rights plan and the tax exempt plan faced similar levels of opposition.
Ratification of the prior issue of 169,132,089 shares, the ratification of the prior issue of 10,224,698 shares to Bergen Asset Management and the issue of shares on conversion of the interest component of the 2013 convertible notes were passed by wider margins.
The company's most recent Appendix 3B new issue announcement said that Suda had 925,687,139 shares on issue, meaning that the votes against Mr Stewart's package amounted to 5.9 percent of the company, sufficient to requisition extraordinary general meetings.
Suda was up 0.2 cents or 4.1 percent to 5.1 cents with 5.4 million shares traded.

ACRUX

United Super, as trustee for Cbus Superannuation, has become a substantial shareholder in Acrux with 8,389,935 shares or 5.04 percent of the company.
United Super said it had acquired 1,924,830 shares between December 31, 2013 and May 7, 2014 in a large number of trades, with the most recent 96,472 shares for $97,467 or $1.01 a share.
Cbus is one of the original compulsory industry superannuation funds and is chaired by former Victoria Premier Steve Bracks.
Acrux was up half a cent or 0.5 percent to 99 cents with 1.4 million shares traded.

GI DYNAMICS

GI Dynamics says that Polaris Venture Partners, Domain Partners V and DP V Associates reduced their holding from 22,267,685 CDIs to 21,746,344 CDIs and were diluted from 5.56 percent to 4.59 percent.
GI Dynamics said it had raised $34.3 million in a placement at 52 cents per Chess depositary interest (CDI) and had allotted 65,951,265 CDIs.
GI Dynamics said the registered holders were Domain Partners V and DP V Associates but lodged the substantial shareholder notice on behalf of Polaris Venture Partners.
The company provided no explanation for the relationship between Polaris and Domain
GI Dynamics was up two cents or four percent to 52.5 cents.

GI DYNAMICS

GI Dynamics says that Johnson & Johnson Development Corp has reduced its holding from 30,130,115 CDIs to 29,586,311 CDIs and was diluted from 7.53 percent to 6.25 percent.

GI DYNAMICS

GI Dynamics says that ATV Associates' holding of 33,638,773 CDIs has been diluted from 8.40 percent to 7.10 percent.
GI Dynamics says that Medtronic Inc's holding of 39,115,442 CDIs has been diluted from 9.77 percent to 8.26 percent.
GI Dynamics says that Greenlight Capital's holding of 28,301,887 CDIs has been diluted from 7.07 percent to 5.98 percent.

UNILIFE CORP

Unilife says it has appointed John Ryanas a senior vice-president, general counsel and company secretary.
Unilife said that vice president, general counsel, corporate secretary and chief compliance officer Christopher Naftzger would be vice-president of legal affairs.
The company said that Mr Ryan had "nearly two decades of legal experience in contract negotiations, corporate compliance, commercial and government litigation and regulatory matters".
Unilife said that previously Mr Ryan was a partner at law firm Duane Morris, representing healthcare, financial and managed service companies across areas including contract negotiation, dispute resolution, consumer class action litigation and antitrust cases.
The company said that Mr Ryan held senior roles at Aramark Corp including as chief counsel and began his legal career as an assistant district attorney at the Manhattan District Attorney's Office.
Unilife said Mr Ryan was a graduate of Northwestern University School of Law and New York University.
Unilife was unchanged at 54.5 cents.

RHINOMED

Rhinomed says it has appointed Tour de France green jersey winner and Orica Green Edge rider Baden Cooke as the Breatheassist Turbine brand ambassador in Europe.
Rhinomed said the appointment bolstered the company's team "as it continues to drive growth of its sports product the Turbine in the Australian and international markets".
The company said that Mr Cooke was one of Australia's most successful racing cyclists who competed professionally between 2000 and 2013.
Rhinomed was unchanged 1.9 cents with 1.6 million shares traded.