Biotech Daily

Wednesday April 30, 2014

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: CELLMID UP 16%, PHARMAXIS DOWN 8%**

*** BIOTA FALLS 34% ON BARDA 'FLU DRUG 'STOP-WORK'**

*** VICTORIA'S $18m TO PROMOTE HEALTH, MEDICAL RESEARCH PLAN**

*** US PATENT FOR MIREVEN'S MICRO-RNA TECHNOLOGY**

*** CELLMID MIDKINE SYMPOSIUM PRESENTS NEW FINDINGS**

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*** IMPEDIMED PLAN RAISES $2.35m, TAKES TOTAL RAISED TO $11m**

*** PROGEN'S PHARMASYNTH WINS MEDIGEN PI-88 CONTRACT**

*** NEUREN AGM MODEST DISSENT AGAINST 3.3m CFO, COO FREE RIGHTS**

*** ACUVAX HAS NO CASH**

MARKET REPORT

The Australian stock market edged up 0.05 percent on Wednesday April 30, 2014 with the S&P ASX 200 up 2.5 points to 5,489.1 points. Ten of the Biotech Daily Top 40 stocks were up, 15 fell, 10 traded unchanged and five were untraded. All three Big Cap were up.

Cellmid was the best, up 0.4 cents or 16 percent to 2.9 cents with 15.4 million shares traded. Phosphagenics climbed 5.75 percent; Bionomics, Genetic Technologies and Universal Biosensors were up more than four percent; Oncosil was up 3.1 percent; Cochlear, Optiscan, Resmed and Sirtex rose more than two percent; QRX and Tissue Therapies were up more than one percent; with CSL up 0.7 percent.

Pharmaxis led the falls, down 0.7 cents or 8.1 percent to 7.9 cents with one million shares traded, followed by Atcor down eight percent to 11.5 cents with 121,700 shares traded. Impedimed and Prima lost more than seven percent; Benitec and Living Cell fell more than six percent; Acrux was down 5.9 percent; Anteo, Medical Developments and Nanosonics fell more than four percent; Reva was down 3.2 percent; Clinuvel and Patrys Sirtex shed more than two percent; Neuren fell 1.1 percent; with Mesoblast down 0.2 percent.

BIOTA PHARMACEUTICALS

Biota fell 34 percent on the Nasdaq following a ‘stop-work’ order on its $US231 million BARDA laninamivir octanoate anti-influenza drug contract (BD: Apr 1, 2011).

Biota said that it had been notified by the US Department of Health and Human Services office of the Assistant Secretary for Preparedness and Response and the Biomedical Advanced Research and Development Authority (BARDA) that “pending a decision regarding the outcome of a recently completed in-process review of the company’s contract ... [they had] issued a stop-work order notifying the company to discontinue work on a number of activities under its contract”.

Biota chief executive officer Russell Plumb said the company was “surprised by this stop-work order and unfortunately, do not have any additional visibility or understanding at this time as to the nature of ASPR [and] BARDA’s pending decision”.

“We anticipate that this decision will be forthcoming shortly and we will provide a further update at that time,” Mr Plumb said.

“In the interim, we are complying with the order and focusing our efforts on critical path activities for the program not covered by the order, namely completing the conduct of and finalizing the data from our phase II Igloo trial,” Mr Plumb said.

Mr Plumb told Biotech Daily “this appears to be an interim communication pending a second communication”.

“We have been advised by ASPR [and] BARDA that the decision ... should be communicated to us shortly, which we believe means this week or next,” Mr Plumb said. “Again, we do not know the nature of this decision at this time.”

Late last year, Biota said it had begun dosing patients in the Northern Hemisphere part of its phase II, clinical trial of laninamivir octanoate (BD: Dec 6, 2013).

Biota said at that time that the 636-subject, randomized, double blind, placebo controlled, parallel arm ‘Igloo’ trial, would compare the safety and efficacy of 40mg and 80mg of its long acting neuraminidase inhibitor laninamivir octanoate with placebo, delivered by its Twincaps inhaler in adults with presumed influenza A or B infection.

Biota began the phase II trial in the Southern Hemisphere in July 2013 (BD: Jul 17, 2013).

Today, Biota said that the contract provided that the Assistant Secretary for Preparedness and Response and BARDA would conduct in-process reviews in its discretion during the performance period to discuss the progress of milestones and deliverables.

Biota said the in-process review was the first since the contract began and was conducted by the Public Health Emergency Medical Countermeasures Enterprise, led by Assistant Secretary for Preparedness and Response and in addition to BARDA, included Department of Health and Human Services partners the Centers for Disease Control and Prevention, the Food and Drug Administration and the National Institutes of Health.

Biota said that as a result of the stop-work order and exceeding the recruitment target of 636 patients in its phase II Igloo trial, it had concluded enrollment in the Northern Hemisphere and would not enroll patients during the Southern Hemisphere influenza season.

The company said that virology data to-date indicated that about 40 percent of the patients enrolled in the trial had laboratory confirmed influenza A or B.

Biota said it expected top-line results from the trial to be available by October 2014.

Biota has about 10,000 Australian investors whose holdings have been migrated to the Nasdaq, but most recently only about 200 had set up accounts to be able to trade the shares.

Last night on the Nasdaq, Biota fell $US1.89 or 33.9 percent to $US3.68 ($A3.97, equivalent to 49.6 cents pre-merger) with 1,035,101 shares traded.

VICTORIA GOVERNMENT

The Victoria Government has promised $17.8 million over three years to promote the health and medical research sector “to boost exports and jobs”.

In a launch at the Walter and Eliza Hall Institute for Medical Research, Victoria’s Deputy Premier and Minister for State Development Peter Ryan and Minister for Health David Davis spoke of the positive attributes of the health, medical research and biotechnology sector and said the State needed to capitalize further on its assets.

The Ministers provided little detail about where the funds would be allocated but mentioned support for overseas trade missions, Victorian Government Business Offices of which there were five in China alone, as well as local conferences.

A summary document provided with the ‘Global Health Melbourne Plan – Taking Victoria’s health strengths to the world’ said the Plan would promote Victoria’s health system, policy and design as well as medical research “as well as identify investment opportunities to strengthen Victoria’s [research and development] capability”.

The document said the Plan would support the attraction of more high profile international health sector conferences to Melbourne, the increase of overseas students enrolled in Victorian courses in health related training particularly in aged-care and growth in the export of medical devices, scientific equipment and digital health.

Mr Ryan said that the health and medical research sector was “a major jobs generator in Victoria” and with $2.6 billion a year in exports was the third highest sector for the State after food and fibre and educational export income.

“Victoria leads the world in health system policy and design; medical research; workforce training; facility design, construction and management; provision of medical services; manufactured products and related know how; and the hosting of health and medical conferences,” Mr Ryan said.

Mr Ryan said the $5 million deal between the Burnet Institute and the Beijing-based Guominxinhe Investment Fund for point-of-care diagnostic tests “shows what can be achieved when Victorian organizations form relationships overseas” (BD: Apr 14, 2014).

“This Plan aims to harness growing demand for Victorian health services, technology and research in countries such as China, Indonesia and Malaysia, where the middle class is expanding and governments are spending more on health,” Mr Ryan said.

Mr Davis said Victoria was recognized around the world for its health care.

“The health and aged care services offered here are second to none and Victoria is world renowned for its health system, the quality of care offered and pioneering work in preventing chronic diseases,” Mr Davis said.

“Victoria is recognized internationally for outstanding medical research and is home to four of Australia’s largest independent medical research institutes: the Walter and Eliza Hall Institute, the Murdoch Children’s Research Institute, the Burnet Institute and the Baker IDI Heart and Diabetes Institute,” Mr Davis said.

“Our health and medical research sector attracts around $1 billion in research-related income annually, more than any other state in Australia,” Mr Davis said.

Mr Davis said Victoria was a leading destination for the world’s largest and most prestigious medical conferences, with six major medical conferences taking place in Melbourne in 2013-‘14.

“Victoria is home to outstanding examples of cutting edge healthcare infrastructure such as the Victorian Comprehensive Cancer Centre, the new Bendigo Hospital and the Royal Children’s Hospital, which has won over 30 national and international architecture and design awards,” Mr David said.

The Global Health Melbourne Plan is at: www.vic.gov.au/globalhealthmelbourne.

MIREVEN

Mireven says the US Patent and Trademark Office has granted its first US patent covering its micro-RNA miR-7-5p anti-cancer technology (BD: Feb 12, 2013).
Mireven said the patent was entitled 'Method Of Modulation of Expression of Epidermal Growth Factor Receptor (EGFR) Involving miRNA'.
The company said that founding scientists Prof Peter Leedman and Dr Keith Giles, along with Dr Rebecca Webster, were named inventors on the patent.
Mireven said it was commercializing discoveries from the Harry Perkins Institute of Medical Research at the Nedlands, Western Australia Queen Elizabeth II Medical Centre.
Mireven said it had worldwide exclusive rights to the patent through its technology licence from the University of Western Australia, as well as to other miR-7-related patent applications at various stages of prosecution in key markets around the world.
The company said that miR-7 was part of a recently discovered family of small, regulatory molecules that have the ability to regulate families of genes inside cells and miR-7 regulated genes involved in cancer and resistance to cancer therapy.
Mireven said that by developing miR-7 as a micro-RNA replacement therapy it hoped to provide additional therapeutic options for difficult to treat cancers.
Prof Leedman said that the patent "validates the Institute's parallel strategies of high-profile scientific publication output combined with protection of intellectual property value, without which our discoveries cannot be translated into potentially life-saving developments in cancer therapy."
Mireven is a private company funded by investments from the Medical Research Commercialisation Fund, managed by Melbourne's Brandon Capital.

CELLMID

Cellmid says that its third midkine symposium has discussed "significant new findings on midkine biology, manufacture and clinical utility".
Cellmid said that the discoverers of midkine Prof Takashi Muramatsu and Prof Kenji Kadomatsu co-hosted the event held in Kyoto, Japan.
The company said that serum-stable, drug-like midkine manufacture had been achieved at large scale for clinical use by one of its company's commercial partners, which was "a major milestone" for its midkine protein programs and that anti-midkine antibodies had been shown to overcome drug-resistance in the brain cancer glioma in pre-clinical efficacy studies conducted by Complutense University's Dr Guillermo Velasco in Madrid, Spain.
The company said that its anti-midkine antibody enhanced bone fracture healing in-vivo in animal studies conducted by Germany's University of Ulm's Dr Astrid Liedert.
Cellmid said that insights into midkine's molecular structure and its functional implications were presented by National University of Singapore Prof Christoph Winkler and the Zhejiang Provence, China-based Huzhou Hospital's Prof Licheng Dai and that several scientists provided "further understanding of the receptors and signalling pathways engaged by [midkine] in cancer and other diseases ... in in-vitro and in-vivo studies".
Cellmid said that Advangen scientists presented information on how midkine controlled the expression of key genes in the hair follicle that kept the follicle alive and active, providing mechanism of action data on how midkine promoted hair growth.
The company said that the Munich, Germany-based Ludwig-Maximillians University's Dr Ludwig Wechback presented on the 'recise mechanism of action by which midkine promoted inflammatory cell infiltration into tissues, giving clear insights into how anti-midkine treatments might disrupt this process.
Cellmid was up 0.4 cents or 16 percent to 2.9 cents with 15.4 million shares traded.

BIODIEM

Biodiem says it will collaborate with the University of Western Sydney on BDM-I's activity against hospital pathogens such as methicillin-resistant Staphylococcus aureus.
Biodiem said the University's Antibiotic Resistance and Mobile Elements Group led by Dr Slade Jensen would investigate the mechanism of action of BDM-I against pathogens such as methicillin-resistant Staphylococcus aureus (MRSA) or 'golden Staph'.
The company said that strains of MRSA were not only a major cause of healthcare-associated infections around the world, but were an emerging cause of infections in the wider community and that MRSA accounted for about 24 percent of Staphylococcus aureus bloodstream infections and was associated with increased health-care costs, morbidity and mortality.
The company said that vancomycin was considered the mainstay of therapy for invasive MRSA infections, but intermediate vancomycin resistance had emerged, which could be associated with treatment failure and there were concerns about the toxicity and effectiveness of alternative antimicrobial treatments.
Biodiem said that BDM-I had demonstrated activity against a broad range of microorganisms, including Gram-positive hospital pathogens, such as vancomycin-resistant enterococci and methicillin-resistant Staphylococcus aureus.
The company said the mechanism of action of BDM-I was unknown but previous experiments indicated that its cellular target was novel and a next-generation anti-infective.
Biodiem said it was seeking potential sub-licencees and formulation partners for BDM-I.
Biodiem is a public unlisted company.

GI DYNAMICS

GI Dynamics closed a scheduled quarterly results teleconference to announce has trading halt relating to a proposed capital raising.
At 8am (AEST) GI Dynamics chief executive officer Stuart Randle spoke briefly to the teleconference to announce that the company was requesting a trading halt, but gave no details and took no questions.
At 8.44am the company posted its trading halt request to the ASX saying that it was "in the process of conducting a capital raising and is requesting this trading halt to allow sufficient time to complete the capital raising".
Trading will resume on May 2, 2014 or on an earlier announcement.
Separately, the company released its Appendix 4C for the three months to March 31, 2014 showing income of $902,000 for sales of its Endobarrier obesity and diabetes technology, compared to $356,000 for the three months to March 31, 2013 and $1,060,000 for the three months to December 31, 2013.
GI Dynamics said it had a net operating cash burn of $9,718,000 for the three months to March 31, 2013 and cash at March 31, 2014 of $49,486,000.
GI Dynamics last traded at 52 cents.

IMPEDIMED

Impedimed says its share purchase plan at 19.5 cents a share has raised about $2.35 million.
Impedimed said that with its $8.8 million placement it had raised about $11.15 million to commercialize its L-Dex system in the US lymphoedema market (BD: Mar 28, 2014).
Impedimed fell 1.5 cents or 7.1 percent to 19.5 cents.

PROGEN PHARMACEUTICALS

Progen says Medigen Biotechnology has engaged wholly-owned subsidiary Pharmasynth to manufacture and project manage PI-88 registration batches.
The Taiwan based Medigen is a 19.7 percent owner of Progen and licencee of its PI-88 compound for liver cancer (BD: May 29, 2013).
Progen said that data generated from the services would be included in the chemistry, manufacturing and control sections of the new drug application and Medigen had consulted with the Taiwan Food and Drug Administration on the final PI-88 chemical formulation for large scale manufacture.
The company said that Medigen expected to complete all registration batches of PI-88 by the third quarter of 2014.
Progen said that Medigen was completing the fully-recruited randomized, placebo-controlled phase III 'Patron' trial in Taiwan, South Korea, China and Hong Kong to confirm the safety and efficacy of PI-88 in the adjuvant treatment of hepatocellular carcinoma after surgical resection.
The company said that if the interim results were in line with expectations, Medigen expected to lodge the accelerated application with the Taiwan FDA this year.
Progen said that Pharmasynth previously manufactured PI-88 for the Patron trial and project managed the fill, finish, labelling and distribution.
Progen was untraded at 99 cents.

NEUREN

Neuren annual general meeting faced about 9.4 percent opposition to the issue of 3,309,892 free 'performance' rights to executives Jon Pilcher and James Shaw.
A total of 37,604,806 proxy votes (9.4%) opposed the issue of the performance rights to chief financial officer Mr Pilcher with 363,253,209 proxy votes (90.6% in favor).
A similar margin opposed the issue of rights to chief operating officer Mr Shaw.
The issue of 20 million loan shares to Mr Pilcher and 10 million loan shares to Mr Shaw at 9.2 cents a share, was opposed by more than 16.9 million votes and supported by more than 366.4 million votes.
All other resolutions including the re-election of director Bruce Hancox and a special resolution requiring a 75 percent majority to remove the constitutional requirement for two New Zealand-based directors were passed overwhelmingly (BD: Mar 27, 2014).
The company's most recent Appendix 3B new issue announcement said Neuren had 1,545,502,173 shares on issue, meaning the votes against the performance rights amounted to 2.4 percent of the company, not sufficient to requisition extraordinary general meetings.
Neuren fell 0.1 cents or 1.1 percent to 8.7 cents with 2.6 million shares traded.

ACUVAX

Acuvax says its net operating cash burn for the three months to March 31, 2014 was $31,000 with no cash at the end of the quarter.
Acuvax provided no further information
Acuvax was untraded at 0.1 cents.