Biotech Daily

Tuesday March 20, 2018

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: OSPREY UP 14%; STARPHARMA DOWN 6%**

*** PHOSPHAGENICS, TERUMO 'FOCUS ON TPM INJECTABLES'**

*** INVION, HUDSON COLLABORATE ON PHOTO-THERAPY FOR CANCER**

*** FDA ACCEPTS PSIVIDA DURASERT POSTERIOR UVEITIS NDA FILING**

*** FDA ACCEPTS MAYNE ANDA FOR INTRAVAGINAL CONTRACEPTIVE**

*** BIOTECH DAILY EDITORIAL CORRECTION, CORRECTION**

*** MICRO-X TAKES CAPITAL RAISING HALT TO SUSPENSION**

*** BARD1 REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** NY EMPERY TAKES 9% OF IMMURON**

*** MEDICAL DEV DAVID WILLIAMS SELLS 5m SHARES 'TO MEET DEMAND'**

*** PRO MEDICUS DR SAM HUPERT, ANTHONY HALL SELL 2m SHARES**

MARKET REPORT

The Australian stock market fell 0.39 percent on Tuesday March 20, 2018, with the ASX200 down 23.0 points to 5,936.4 points. Fifteen of the Biotech Daily Top 40 stocks were up, 12 fell, 11 traded unchanged and two were untraded.

Osprey was the best, up 3.5 cents or 14.3 percent to 28 cents with 449,035 shares traded. Orthocell climbed 12.3 percent; Benitec and Optiscan were up five percent or more; Bionomics, Clinuvel and Immutep improved more than four percent; Ellex was up 3.45 percent; Factor Therapeutics and Medical Developments rose more than two percent; Admedus and Avita were up more than one percent; with Psivida, Resmed, Sirtex and Viralytics up by less than one percent.

Starpharma led the falls, down seven cents or 5.8 percent to $1.13 with 1.7 million shares traded. Opthea and Universal Biosensors lost five percent or more; Pharmaxis fell 4.55 percent; Airxpanders and Prana were down more than three percent; CSL, Impedimed, Mesoblast and Polynovo shed more than one percent; with Cochlear, Nanosonics, Neuren and Pro Medicus down by less than one percent.

PHOSPHAGENICS

Phosphagenics says its research and development alliance with Terumo Corp, initially designed to explore tocopheryl phosphate mixture patches, will focus on injectables.

In 2016, Phosphagenics said Terumo had a tocopheryl phosphate mixture (TPM) oxymorphone patch option licence, and a research and development alliance for the three additional pharmaceutical products covering multiple other TPM-based, non-patch assets (BD: Apr 29, Jul 29, 2016).

Today, the company said Terumo had terminated the development agreement associated with the development of a one-day TPM-oxymorphone patch, specifically designed for the Japanese market, and the companies had begun discussions on TPM injectables.

Phosphagenics said that all rights and obligations associated with the TPM-oxymorphone patch program would revert to Phosphagenics and all patch activities would be directed towards the requirements of the broader global market, namely a three-day patch.

The company said the shift in focus was “the result of a number of alliance projects achieving key decision points, most notably the success of the TPM-propofol program and the challenges Terumo believe exist for a TPM-oxymorphone patch entering the unique Japanese market”.

Phosphagenics chief executive officer Dr Ross Murdoch told Biotech Daily that TPM “has the ability to solubilize molecules that traditionally have been hard to solubilize”.

“People use detergent to solubilize and we can replace itm because TPM has one end that has an affinity to water and the other end has an affinity with oil, making it better for solubilization,” Dr Murdoch said. “There are limitations to detergents and toxic excipients like cremophor that we are replacing with TPM.”

In the media release, Terumo executive Masahito Takahashi said “the technical hurdles we set to ensure the commercial success of an opioid patch in Japan are very high”.

“Terumo remains committed to the TPM technology, TPM-propofol and our … alliance with Phosphagenics,” Mr Takahashi said.

“We are interested in Phosphagenics’ growing portfolio of early stage TPM based injectables and are actively investigating the potential to take on additional projects,” Mr Takahashi said.

Phosphagenics chief executive officer Dr Ross Murdoch said the alliance with Terumo was “strong and productive … most notably demonstrated in the success and rapid progression of the TPM-propofol injectable program which has already entered the formal preclinical/toxicology phase”.

“I believe that the mutual decision to shift the primary focus of our agreement towards injectables is sensible and pragmatic, particularly given Terumo’s strong portfolio of injectable technologies,” Dr Murdoch said.

“The [research and development] alliance has been very beneficial to our patch program,” Dr Murdoch said.

“Redirecting all patch activities back to a three-day TPM-oxymorphone patch so as to address the requirements of the broader market will be relatively seamless and has already begun,” Dr Murdoch said.

“The demands and investment put towards the one-day Japanese patch have benefited us and enabled a number of technical improvements … that should result in our three-day patch being much better suited to address the requirements of the global pain market,” Dr Murdoch said.

Dr Murdoch said that plans for discussions with the US Food and Drug Administration to progress the patch to an investigational new drug application were being formulated and discussions with Terumo over potential injectable projects were ongoing.

Phosphagenics was unchanged at 1.3 cents.

INVION

Invion says it has a research and development alliance agreement with the Hudson Institute of Medical Research to develop its Photosoft technology for cancer.

Invion said that the Hudson Institute, formerly Prince Henry's Institute of Medical Research and Monash Institute of Medical Research, would provide the research facilities and expertize to undertake its sponsored research projects on its Photosoft "next generation photo dynamic therapy" and the Institute would be responsible for all legislative and professional standards compliance requirements.

The company said that the therapy used "non-toxic photo-sensitizers and visible light in combination with oxygen to produce cytotoxic-reactive oxygen" that killed malignant cells, shut down tumors and stimulated the immune system.

Invion said that in contrast to surgery, or radiotherapy and chemotherapy which were mostly immunosuppressive, the photo-therapy caused acute inflammation, expression of heat-shock proteins and invasion and infiltration of tumors by leukocytes.

The company said that as a next generation photo dynamic therapy Photosoft was targeted to address the limitations of first generation therapies through better solubility and tissue distribution, as well as stronger absorption allowing deeper penetration of tissues and better tumor specificity.

Invion said that Photosoft used a laser light activation method based on short, pulsating near infrared wavelengths, which was hypothesized to allow more effective whole-of-body systemic treatment to target circulating cancer cells as well as deeply seated tumors.

The company said that initial projects would focus on ovarian cancer and it was expected that projects would expand quickly to other indications.

Invion said that the Cho Group would provide non-dilutive funding to cover its obligations for all research projects undertaken by Hudson Institute.

Invion climbed 0.8 cents or 42.1 percent to 2.7 cents with 98.7 million shares traded.

PSIVIDA CORP

Psivida says the US Food and Drug Administration has accepted its new drug application for Durasert three-year treatment for posterior segment uveitis.

Psivida said the acceptance "reflects the FDA's determination that the application is sufficiently complete to permit a substantive review".

The company said that the application would be subject to a standard review and have a Prescription Drug User Fee Act (PDUFA) date of November 5, 2018, which was the goal date for the FDA to complete its review.

Psivida said the NDA included data from two phase III studies which showed that each achieved the primary efficacy endpoint at six months ($p < 0.001$).

The company said that Durasert had a safety profile consistent with the safety profile of steroid treatments currently considered standard-of-care.

Psivida chief executive officer Nancy Lurker said the FDA acceptance was "a major milestone".

"Given the high unmet medical need, we believe that Durasert, if approved, has the potential to become an important new treatment option for the thousands of patients suffering from posterior segment uveitis, the third leading cause of blindness," Ms Lurker said.

Psivida was up half a cent or 0.3 percent to $1.63.

MAYNE PHARMA GROUP

Mayne says the US Food and Drug Administration has accepted its abbreviated new drug application for its generic Nuvaring intra-vaginal hormonal contraceptive device.
Mayne said that Nuvaring combined etonogestrel and ethinyl estradiol delivered over a three-week period.
The company said that in February 2017, it signed a licence and supply agreement with the Liege, Belgium-based Mithra Pharmaceuticals SA, which would be responsible for supply of the product, while Mayne would be responsible to market, sell and distribute the product following FDA approval (BD: Feb 28, 2017).
Last year, Mayne said that Mithra was developing a generic Nuvaring which it called Myring.
The company said that Merck's Nuvaring had US sales of about $US830 million for the 12 months to January 31, 2018.
Mayne chief executive officer Scott Richards said the acceptance was "an important regulatory milestone".
"Generic Nuvaring is a complex and difficult-to-develop and manufacture product and complements our existing women's health franchise of 21 marketed products," Mr Richards said.
"Following the Teva portfolio acquisition, Mayne Pharma became the second largest supplier of oral contraceptives in the US," Mr Richards said.
"Nuvaring is the largest contraceptive sold in the $US5.6 billion US contraceptive market with no generic equivalents," Mr Richards said.
Mr Richards said that he expected to commercialize generic Nuvaring by July 2019.
Mayne was up 2.5 cents or 3.4 percent to 77 cents with 10.98 million shares traded.

BIOTECH DAILY EDITORIAL CORRECTION, CORRECTION

Last week's editorial on 'Doing the Deal' listed a number of important Australian innovations and erroneously claimed medical penicillin as one of ours. The subsequent correction was incorrect. Yes, this is embarrassing (BD: Mar 13,14, 2018).
In fact, the Australian connection was that Australian-born Oxford professor Prof Howard Florey followed up the work of penicillin discoverer, Prof Alexander Fleming at St Mary's Hospital, London.
Prof Florey's work was carried out in Oxford, England with several other key researchers including Dr Ernst Chain, a German Jewish refugee, Dr Norman Heatley and Dr Edward P Abraham.
The work of Florey's Oxford Team was funded mainly by the UK Medical Research Council.
Fleming, Chain and Florey were awarded the 1945 Nobel Prize for Physiology or Medicine "for the discovery of penicillin and its curative effect in various infectious diseases".
Several sub-editors have been terminated.

MICRO-X

Micro-X has requested a voluntary suspension to follow the trading halt requested on March 16, "pending the release of an announcement to the market in relation to a capital raising" (BD: Mar 16, 2018).
Micro-X last traded at 40 cents.

BARD1 LIFE SCIENCES

Bard1 has requested a trading halt pending “an announcement regarding a capital raising”.
Trading will resume on March 22, 2018 or on an earlier announcement.
Bard1 last traded at 2.3 cents.

IMMURON

The New York-based Empery Asset Management has become a substantial shareholder in Immuron with 13,162,744 shares or 9.22 percent.
Last week, Immuron said it had raised $5,133,470 from an unnamed “large US institutional investment fund” in a placement at 39 cents a share but did not disclose the identity of the fund (BD: Mar 14, 2018).
In a substantial shareholder notice today, Empery managing member Ryan Lane said that the holders included himself, Marin Hoe, Empery Asset Management, Empery AM GP, Empery Asset Laster, Empery Tax Efficient LP and Empery Tax Efficient II LP, with Citicorp the registered holder.
Mr Lane said the group acquired the shares on March 16, 2018 for $5,133,470 or 39 cents a share and said it would be issued with 7,897,647 warrants over shares, exercisable at 46.8 cents each within five years of issue.
In 2016, Empery was one of four investment groups stopped by a Bionomics extraordinary general meeting from being issued 16,082,988 warrants over shares, following a $16 million placement (BD: Dec 8, 2015; Mar 3, 2016).
The warrants were exercisable at 59.38 cents a share within five years of issue.
In 2015, Empery become a substantial shareholder in Orthocell with 5,325,759 shares or 6.455 percent, acquired at 49.3 cents a share (BD: Nov 24, 2015).
Immuron fell one cent or 2.6 percent to 38 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments chairman David Williams says he has reduced his holding from 13,694,874 shares (23.17%) to 8,671,045 shares (14.67%).
In his substantial shareholder notice Mr Williams said he sold 5,000,000 shares off-market at $7.50 a share to meet a “strong demand for shares”.
Mr Williams told Biotech Daily that the balance of 23,829 shares were transferred to his son, Ward Williams’ account.
Mr Williams said that Medical Developments “recently completed a three-week road show where 48 financial institutions from Europe, Asia and Australia were presented the … story”.
“As a result of those meetings there was strong demand for shares and for more liquidity from a number of financial institutions through Jefferies Securities of Hong Kong and Bell Potter in Australia”.
Mr Williams said he remained the company’s biggest shareholder and was “delighted and proud of the progress [Medical Developments] is making and I view the strong demand from financial institutions as a vote of confidence,” Mr Williams said.
“I am told the shares sold yesterday went to funds in Australia, US and UK,” Mr Williams said.
The substantial shareholder notice said that the registered holders of the shares were Lawn Views Pty Ltd, Moggs Vreek Pty Ltd and Kidder Peabody Pty Ltd.
Medical Developments was up 21 cents or 2.9 percent to $7.46.

PRO MEDICUS

Pro Medicus co-founders, chief executive officer Dr Sam Hupert and technology director Anthony Hall say they have sold 1,000,000 shares each.

In directors' interest notices and a separate announcement to the ASX, Dr Hupert and Mr Hall said that between March 14 and 19, 2018 they sold the shares at prices ranging from $8.00 to $8.52 each.

Pro Medicus said that Dr Hupert retained 29,107,660 shares or 28.2 percent of the company and Mr Hall held 29,067,500 shares or 28.1 percent.

In its half yearly report, Pro Medicus said that "in order to improve the liquidity in the company's shares, the board is encouraging the founders to consider selling up to three million shares each, which is … less than 10 percent of their holdings" with any sales to be made within 12 months of the report (BD: Feb 16, 2018).

Pro Medicus fell six cents or 0.7 percent to $8.14.