Biotech Daily

Thursday November 16, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: NEUREN UP 22%; ACTINOGEN, UNIVERSAL BIO DOWN 6%**

*** PATRYS, WEHI COLLABORATE ON 7D10, PAT-DX1 FOR CANCER**

*** US QIDP STATUS FOR RECCE-327 FOR E COLI, GOLDEN STAPH**

*** US PATENT FOR PHARMAUST AADS FOR CANCER**

*** PRIMA EXPECTS TO FILE US IMP321 IND BY JULY 2018**

*** NOXOPHARM TREATS 1st NOX66 PROSTATE CANCER PATIENT**

*** ESENSE, HEALTHY CHOCOLATE DEVELOP MARIJUANA CHOCOLATE**

*** MEDADVISOR TO RELEASE 89m SHARES FROM ESCROW**

*** STEMCELL HOPES TO RAISE $2.3m**

*** ANTEO AGM LOSES DIRECTOR, SURVIVES REM REPORT, AGAIN**

*** FACTOR AVOIDS AGM 1st STRIKE BY 0.75%**

*** UP TO 19% OF MESOBLAST OPPOSE REMUNERATION REPORT**

*** CREDIT SUISSE RETURNS, SELLS BELOW 5% OF MESOBLAST**

*** PARADICE INVESTMENTS TAKES 6% OF IMPEDIMED**

*** W WHITNEY GEORGE TAKES 19% OF RHINOMED**

MARKET REPORT

The Australian stock market was up 0.16 percent on Thursday November 16, 2017, with the ASX200 up 9.3 points to 5,943.5 points. Fifteen of the Biotech Daily Top 40 stocks were up, 12 fell, nine traded unchanged and four were untraded.

Neuren was the best, up 2.5 cents or 21.7 percent to 14 cents with 10.6 million shares traded. Compumedics was up 8.7 percent; Ellex and Impedimed climbed more than four percent; Volpara was up three percent; Bionomics, Factor Therapeutics, Osprey, Polynovo and Sirtex rose two percent or more; Clinuvel, Cochlear and Cyclopharm were up more than one percent; with Medical Developments, Nanosonics, Pro Medicus and Resmed up by less than one percent.

Actinogen and Universal Biosensors led the falls, both down 5.6 percent to 5.1 cents and 34 cents, respectively, with 181,428 and 296,147 shares traded, respectively. Living Cell, Mesoblast and Viralytics lost more than three percent; Airxpanders, Benitec, Dimerix and Starpharma shed more than two percent; LBT, Pharmaxis and Prana were down more than one percent; with CSL down 0.4 percent.

PATRYS, WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

Patrys says it has a collaboration with the Walter and Eliza Hall Institute combining its PAT-DX1 with WEHI's 7D10 antibody to kill cancer through a new pathway.

Patrys said the program would be led by the Institute's head of cancer molecular genetics Dr Ruth Kluck who had been investigating cancer cell death pathways since 2002 as well as how cell-killing proteins such as Bax and Bak were regulated and implicated in cell death.

The company said that the collaboration would couple PAT-DX1 with 7D10 to generate a bi-specific antibody with the potential to kill cancer cells through a new pathway.

Patrys said that previous studies had shown that once inside cells 7D10 interacted with the Bak protein to cause cell death, but a technology to reliably deliver 7D10 into cells had not been identified.

The company said that with its Yale University collaborators it had shown that PAT-DX1 targeted tumors and could enter and kill cancer cells.

Patrys said that combining the two technologies by the generation of a bi-specific 7D10-PAT-DX1 antibody would result in a new antibody that "should be able to enter a cell, bind to its target and act to help circumvent survival pathways typically employed by cancer".

Patrys chief executive officer Dr James Campbell said that the company "looks forward to exploring the potential for development of a first-in-class, bi-specific, cancer antibody with the Institute".

"The collaboration should provide data regarding the potential effectiveness of 7D10-PAT-DX1 against breast cancer cells and as a possible treatment for a range of other cancers," Dr Campbell said.

Patrys was up 0.1 cents or 6.25 percent to 1.7 cents with seven million shares traded.

RECCE

Recce says the US Food and Drug Administration has granted Recce-327 qualified infectious disease product (QIDP) designation.

Recce said the designation was for Recce-327 as a broad spectrum antibiotic, used intravenously against Escherichia coli and Staphylococcus aureus bacteria in the blood, including their superbug forms, which could lead to potentially fatal sepsis, or blood poisoning.

The company said that through the designations Recce-327 was labeled for fast track designation to speed the FDA's review process.

Recce said that if Recce-327 completed the necessary clinical trials and wa approved by the FDA, the designation would provide five years of market exclusivity, starting from the date of new drug application approval, extended for another five years through Hatch-Waxman exclusivity, with additional protection from the company's patents.

Recce executive chairman Dr Graham Melrose said "the fact that Recce-327 meets the FDA's criteria for qualified infectious disease product designation is a tremendous validation of our strategy to invest in synthetic polymers as potentially a whole new-class of antibiotics".

"Our plans for Recce-327 are on track to progress its development towards clinical testing in humans; we are encouraged that it has the potential to play an important role in the global challenge of antibiotic resistance," Dr Melrose said.

Recce was up one cent or 5.7 percent to 18.5 cents with 2.4 million shares traded.

PHARMAUST

Pharmaust says it has been granted a US patent covering its library of amino-acetonitrile derivative compounds, originally developed by Tokyo's Nihon Nohyaku.

Pharmaust said the patent, entitled 'Anticancer Agent comprising Aminoacetonitrile Compound as Active Ingredient', protected the compounds until September 2034.

The company said the amino-acetonitrile derivative (AAD) compounds were related to, but distinct from, monepantel, which it was developing as an anti-cancer therapy.

Pharmaust chief executive officer Dr Richard Hopkins said the "allowance of this patent secures Pharmaust's ownership for over 50 novel AAD compounds".

"Having ownership of these compounds, which have already been shown to have anti-cancer activity, enables Pharmaust to develop its own pipeline of new cancer drugs," Dr Hopkins said.

"We have now engaged our subsidiary Epichem to synthesize and optimize selected candidates from our novel AAD library," Dr Hopkins said. "Epichem's drug discovery team specializes in optimizing drugs and has successfully generated a number of novel drugs for its clients that have progressed to clinical trials."

Pharmaust was up 0.2 cents or 4.1 percent to 5.1 cents with one million shares traded.

PRIMA BIOMED

Prima says that it expects to file a US investigational new drug (IND) application for an immuno-oncology combination trial of IMP321 by July 2018.

Prima said that it had a "very productive" pre-IND application meeting with the US Food and Drug Administration to discuss the regulatory pathway for IMP321, which was formerly referred to as LAG-3Ig and was recently referred to as eftilagimod alpha.

The company said that the FDA addressed its questions related to pre-clinical, non-clinical and clinical data and design of clinical trials of eftilagimod alpha in chemo-immunotherapy and in an immuno-oncology combination trial.

Prima chief executive officer Marc Voigt said meeting was "an important milestone".

"Our meeting with the FDA was very productive and their guidance will be most valuable in assessing the … clinical and regulatory strategies for eftilagimod alpha," Mr Voigt said.

Prima was unchanged at 2.4 cents with 3.6 million shares traded.

NOXOPHARM

Noxopharm says it has treated the first of up to 30 patients in a phase I trial of NOX66 with radiation for metastatic castrate-resistant advanced prostate cancer.

In September, Noxopharm said that it would conduct a 24-patient trial of NOX66 with radiation for prostate cancer at five centres in Queensland and New South Wales overseen by the Trans-Tasman Radiation Oncology Group Cancer Research Australia (BD: Sep 27, 2017).

Today, the company said the 'Lupin' study was an investigator-led, prospective, open-label, single-arm trial at Sydney's St Vincent's Hospital, with Dr Louise Emmett as the principal investigator.

Noxopharm said that the study would investigate the safety and efficacy of NOX66 with 177lutetium-PSMA-617 (LuPSMA) in men with metastatic, castrate-resistant prostate cancer that failed to respond to all standard therapies and who had limited prospects.

Noxopharm was up one cent or 1.6 percent to 64.5 cents.

ESENSE-LAB

Esense says that with Healthy Chocolate Florida LLC it has “reached a key milestone” in developing terpene-infused chocolate products.
Esense said it had a joint venture with the Sarasota, Florida-based Healthy Chocolate and had finalized its beta chocolate formulation.
The company previously said it was developing its terpenes to reconstruct essential oils including cannabis and saffron, but did not say which terpenes were in the chocolate.
Esense director Brendan De Kauwe told Biotech Daily that the terpene to be infusion in the chocolate was marijuana.
In its media release, Esense said the finalization of the formulation was “a highly significant breakthrough” for the cannabis food and beverage and food additive industries.
The company said that development was focussed on the finalization of the chocolate product’s consumer-ready qualities and requirements.
Esense fell half a cent or 1.3 percent to 37.5 cents with 3.8 million shares traded.

MEDADVISOR

Medadvisor says that 88,795,906 shares held in ASX escrow will be released for trading on December 1, 2017.
Medadvisor said that the shares to be released were part of 498,800,073 shares and 35,500,000 “Read rights” held in ASX escrow until December 1, 2017 but 410,004,167 shares and the Read rights would remain in voluntary escrow until December 1, 2018, along with the 43,421,055 Healthnotes shares also to be held in voluntary escrow until October 28, 2018.
The company told Biotech Daily that following the ASX escrow release it would have 859,852,760 shares available for trading and 1,313,277,982 shares in the company.
Medadvisor fell 0.3 cents or 5.9 percent to 4.8 cents with 6.1 million shares traded.

STEMCELL UNITED

Stemcell United says it hopes to raise up to $2.3 million in a one-for-five rights issue and private placement at two cents a share.
Stemcell said it planned to lodge an offer document and related documentation with the ASX not later than January 15, 2018.
In September, Stemcell United said that marijuana consultant Nevil Schoenmakers has filed a notice of termination from the company. (BD: Sep 29, 2017)
In March, Stemcell United’s share price rocketed from 1.2 cents to a high of $1.085 on the appointment of Mr Schoenmakers (BD: May 1, 2017).
Stemcell United said in September it was “still intending to expand into medicinal cannabis”, pending regulatory approvals.
Stemcell announced its foray into medical marijuana in March, having changed its name in from On Q Group, which previously said it would extract resina from Daemonorops draco blume (Dragon’s Blood) for traditional Chinese medicines.
On Q said that “whether or not [traditional Chinese medicine] is believed, studies have shown that Chinese herbal medicine can be successful in treating a range of disorders”.
The company said it would begin marketing of its dendrobium essence-infused mask by July 2017 and was in discussion with a Chinese pharmaceutical company on providing consultancy services for manufacturing resina.
Stemcell fell 0.2 cents or 6.1 percent to 3.1 cents with 4.6 million shares traded.

ANTEO DIAGNOSTICS

Anteo's annual general meeting voted against director Alan Studley and narrowly avoided a remuneration report first strike.

Last year, Anteo's annual meeting narrowly avoided a remuneration report first strike with 24.2 percent voting against the report but faced up to 35.3 percent against a 10 percent placement capacity and just before the meeting the company said that chairman Mark Bouris had resigned to spend more time with his other companies (BD: Nov 14, 15, 2016).

Today, Anteo said that Mr Studley's election was opposed by 329,259,182 votes (65.7%) and supported by 171,645,756 votes (34.3%).

The remuneration report was passed with 287,494,265 votes (64.9%) in favor, but with 98,089,619 votes (22.15%) against and 57,281,836 (12.93%) held at the "proxy's discretion" which the company chose not to take to a poll.

The issue of securities under the executive and employee share plan faced 80,498,298 votes (17.6%) in opposition, with the re-election of directors Dr Geoff Cumming and Matthew Sanderson passed by a wider margin.

The company's most recent Appendix 3B new issue announcement said that Anteo had 1,152,756,577 shares on issue meaning that the opposition to Mr Studley amounted to 28.6.8 percent of the company's total shares on issue, sufficient to requisition extraordinary general meetings.

Anteo was unchanged at 1.4 cents.

FACTOR THERAPEUTICS

The Factor remuneration report was opposed by 69,681,338 votes or 24.25 percent, narrowly avoiding a first strike at its annual general meeting.

Factor said that 217,701,796 votes (75.75%) supported the remuneration report.

The company said that 71,646,775 votes (24.90%) opposed the issue of 1,000,000 options to director John Michailidis with 216,091,895 votes (75.10%) in favor, with the 10 percent placement capacity opposed by a smaller margin and Mr Michailidis was elected by an overwhelming majority.

The company's most recent Appendix 3B new issue announcement said that Factor had 730,042,783 shares on issue, meaning that the 71,646,775 votes against Mr Michailidis options amounted to 9.8 percent of the company, sufficient to requisition extraordinary general meetings.

Factor was up 0.1 cents or two percent to 5.1 cents.

MESOBLAST

The Mesoblast annual general meeting passed all resolutions but with significant dissent against the remuneration report.

The remuneration report was opposed by 28,085,191 votes (19.0%), with 119,750,682 votes (81.0%) in favor.

The company's most recent Appendix 3B new issue announcement said that Mesoblast had 470,601,826 shares on issue, meaning that the votes against the report amounted to 5.97 percent of the company, sufficient to requisition extraordinary general meetings.

Mesoblast said that the re-election of directors Donal O'Dwyer and Dr Ben-Zion Weiner were opposed by more than 10.5 million votes with more than 205.5 million votes in favor, while the issue of shares to Cache Holdings and ratification of a placement were passed overwhelmingly.

Mesoblast fell four cents or 3.15 percent to $1.23 with 2.3 million shares traded.

MESOBLAST

Credit Suisse says it has ceased its substantial holding in Mesoblast, having become substantial with 34,783,057 shares (7.39%) earlier this week (BD: Nov 13, 2017).
Today, Credit Suisse said the shares were held under “lending agreements” and it primarily “returned” borrowed shares as well as selling some shares with the single largest sale 29,726 shares for $37,889 or $1.275 a share.

IMPEDIMED

Paradice Investment Management says it has increased its substantial shareholding in Impedimed from 18,853,802 shares (5.04%) to 22,763,711 shares (6.06%).
The substantial shareholder notice said that between October 14, 2016 and November 13, 2017 the Sydney-based Paradice bought 6,103,778 shares for $7,263,337 or $1.19 a share and sold 2,193,869 shares for $1,771,030 or 80.7 cents a share.
The notice said that the shares were held by National Nominees, JP Morgan Nominees, HSBC Nominees and Citicorp Nominees.
Impedimed was up 3.5 cents or 4.1 percent to 88 cents with 1.4 million shares traded.

RHINOMED

W Whitney George says he has increased his holding in Rhinomed from 16,570,121 shares (17.70%) to 17,526,816 shares (18.72%).
The Carlsbad, California-based Mr George said he bought 956,695 shares for $US119,553 ($A157,335) or 16.4 cents a share.
Rhinomed was untraded at 15.5 cents.