Biotech Daily

Tuesday April 10, 2018

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: IMMUTEP UP 12.5%; AIRXPANDERS DOWN 8%**

*** PRESCIENT PTX-200 BREAST CANCER TRIAL: '5 OF 10 RESPOND'**

*** BRANDON, MRCF, FEDERAL GOVERNMENT $8m FOR GLOBAL KINETICS**

*** FACTOR VF001 WOUND TRIAL 70% RECRUITED, RESULTS THIS YEAR**

*** ASIC: STEFAN BOITCHEFF AVOIDS GAOL FOR ANTEO MANIPULATION**

*** RESAPP PLEADS 'CLINICAL STUDIES' TO ASX 50% QUERY**

*** RESAPP PRELIMINARY RESULTS 'EXCELLENT' FOR SLEEP APNOEA TEST**

*** CANADA APPROVES MEDICAL DEVELOPMENTS PENTHROX**

*** TELIX DEAL WITH ENDOCYTE FOR PROSTATE CANCER TEST**

*** CURTIN UNI USES DORSAVI'S VIMOVE FOR LOW BACK PAIN TRIAL**

*** RESPIRI RAISES $3m**

*** MMJ INVESTS $1m IN CANNABIS ACCESS ONLINE PORTAL**

*** G MEDICAL REQUESTS 'ANALYST REPORT RESPONSE' TRADING HALT**

*** SUDA LOSES CHAIRMAN MICHAEL STEWART**

*** PHARMAUST: EPICHEM'S WAYNE BEST CHAIR, DR MARTINE KEENAN CEO**

MARKET REPORT

The Australian stock market was up 0.83 percent on Tuesday April 10, 2018 with the ASX200 up 48.3 points to 5,857.0 points. Fourteen of the Biotech Daily Top 40 stocks were up, 15 fell, five traded unchanged and six were untraded.

Immutep was the best on no news, up 0.3 cents or 12.5 percent to 2.7 cents with 23.2 million shares traded. Telix climbed 7.8 percent; Oncosil improved four percent; Avita and Universal Biosensors were up more than three percent; Actinogen, Clinuvel, Compumedics and Psivida rose more than two percent; Ellex, Mesoblast, Orthocell and Polynovo were up more than one percent; with Medical Developments and Resmed up by less than one percent.

Airxpanders led the falls for the second day in a row, down 1.5 cents or 7.7 percent to 18 cents with 4.8 million shares traded. Bionomics fell 4.4 percent; Osprey lost 3.45 percent; Benitec, Nanosonics, Optiscan and Uscom shed more than two percent; Admedus, Opthea, Pharmaxis and Volpara were down more than one percent; with Cochlear, CSL, Impedimed, Pro Medicus, Starpharma and Viralytics down by less than one percent.

PRESCIENT THERAPEUTICS

Prescient says that of the 10 evaluable patients in its 28-patient, phase Ib trial of PTX-200 for breast cancer five (50%) had an overall response rate, twice the expected rate.

Prescient said that the expected industry average response rate was 25 percent for the chemotherapy drug paclitaxel, alone.

The company said the trial dosed 28 patients, 16 patients in the dose escalation stage, while the expansion cohort comprised a further 12 patients with locally advanced or metastatic human epidermal growth factor receptor 2 (HER2)-negative breast cancer, who received 35mg/m2 of PTX-200, with 80mg/m2 per week of paclitaxel, followed by standard doxorubicin-cyclophosphamide and surgery for locally advanced disease.

The company said that 10 of the 12 expansion patients were evaluable for clinical response, of which five had locally advanced disease and five had metastatic disease.

Prescient said that in patients with locally advanced disease, two patients had pathologic complete responses meaning a complete eradication of cancer.

Prescient said the other two patients were not evaluable.

A table provided with the media release said that of the 10 evaluable patients, two had a complete response, three had a partial response, three had stable disease and two had disease progression.

The company said that the trial evaluated PTX-200 in combination with paclitaxel in women with HER2-negative breast cancer, including oestrogen receptors negative and progesterone negative, or triple negative, and oestrogen positive breast cancer.

Prescient said that triple negative breast cancer did not have any of the three receptors commonly found on breast cancer cells: oestrogen, progesterone and HER2 receptors, and the treatment of triple negative and oestrogen positive with HER2-negative receptor breast cancers had “a high level of unmet clinical need”.

The company said that the trial was conducted at the New York-based Albert Einstein College of Medicine’s Montefiore Medical Centre, led by Prof Joseph Sparano, and the Tampa, Florida-based Lee Moffitt Cancer Centre.

Prescient said that an overall response rate combined complete responses and partial responses and studies on all sub-types of locally advanced breast cancer receiving weekly chemo reported complete response rates ranging from eight to 28 percent, while women with locally advanced oestrogen positive with HER2 negative breast cancer had complete response rates of about 16 percent and an overall response rate of 25 percent.

Prescient said the study focussed on patients with locally advanced disease, and they had two complete responses, three partial responses with a 100 percent overall response rate.

The company said the study was currently in a 26-patient, phase II trial in women with HER2 negative locally advanced breast cancer, with five of the patients in the phase Ib study qualifying for assessment of phase II data.

Prescient said that if three or more complete responses were observed in the first 11 patients, then the phase II trial would expand to a further 15 patients.

The company said that for the purposes of this analysis, two complete responses had been observed in the first five patients.

Mr Yatomi-Clarke said the results was the “most significant clinical milestone to date”.

“We are very encouraged with the results from the phase Ib study, albeit from a relatively small number of patients,” Mr Yatomi-Clarke said.

“Whilst the overall results were pleasing, it was particularly encouraging to see our best responses in women with [oestrogen receptor positive] disease, which is an especially difficult disease to treat, and with poor expected outcomes from current chemotherapy regimes alone,” Yatomi-Clarke said.

Prescient fell two cents or 14.3 percent to 12 cents with 29.7 million shares traded.

BRANDON CAPITAL, FEDERAL GOVERNMENT, GLOBAL KINETICS CORP

Brandon Capital says its Medical Research Commercialisation Fund first investment for the Federal Biomedical Translation Fund is $7.75 million for Global Kinetics.

Brandon said that the investment provided working capital to support Global Kinetics research into Parkinson's disease.

The venture capital firm said that the Melbourne-based Global Kinetics was formed in 2007 to develop and commercialize its Parkinson's Kinetigraph wrist-worn device to measure Parkinson's symptoms and provides reports to support routine care.

Brandon managing-director Dr Chris Nave said that the Federal Government Biomedical Translation Fund had "delivered much needed financial support for Australia's world-leading medical research".

"Global Kinetics is a perfect example of Australia's biomedical capabilities, with the technology taken from concept to commercialization here in Melbourne and the product now being manufactured in Australia and exported to the world," Dr Nave said.

"Global Kinetics' technology is improving the lives of people with Parkinson's disease, with over 25,000 … patient reports delivered around the world to date," Dr Nave said.

"This $7.75 million is part of a series six funding round for the company, taking the total amount raised by the company to over $45 million," Dr Nave said.

Brandon said that the Biomedical Translation Fund was part of the Federal National Innovation and Science Agenda and was a $500 million for-profit venture capital fund pooling public and private capital for investments in companies with medical research projects at advanced pre-clinical, phase I and phase II stages of development. The company said that through its Medical Research Commercialisation Fund, it had been appointed to manage $230 million, the largest pool of allocated funds.

Brandon reported that Global Kinetics had launched an Australian 'Treat to Target' study directed toward advanced management and outcomes in Parkinson's disease and supported by Parkinson's Victoria, the Michael J Fox Foundation and the Shake It Up Australia Foundation.

Global Kinetics is a public unlisted company.

FACTOR THERAPEUTICS

Factor Therapeutics says its phase IIb study of VF001 for venous leg ulcers is 69.05 percent recruited with 116 patients enrolled to the maximum target of 168 patients.

Factor said that screening and recruitment in the three months to March 31, 2018 was among the strongest to date, with 26 patients entering the study compared with 28 in the three months to December 31, 2017.

The company said that the withdrawal rate remained lower than expected and as it approached the end of recruitment it had begun the process of refining the study's final recruitment target, with final results expected before the end of 2018.

Factor said that more patients had completed treatment than initially estimated, so the final recruitment target was expected to be lower than the original 168 patients.

The company said it was planning initiatives to drive recruitment before the Northern summer including advertising campaigns in April to drive toward recruitment of the final patients by June 30, 2018.

Factor said it was preparing two presentations on the VF001 technology and the design and execution of the study, for the Symposium on Advanced Wound Care meeting in Charlotte, North Carolina, which would be an opportunity to further discussions with potential partners.

Factor was untraded at four cents.

AUSTRALIAN SECURITIES AND INVESTMENTS COMMISSION, ANTEO

The Australian Securities and Investments Commission says Stefan Mark Boitcheff has escaped gaol for manipulating Anteo's share price in 2013 and 2014.

ASIC said that Mr Boitcheff was sentenced to one year and nine months imprisonment, with an order that he be released immediately on entering into a recognisance to be of good behaviour for two years.

Last year, ASIC said that Mr Boitcheff, then 31, a day-trader of Virginia, South Australia pleaded guilty in the District Court of South Australia to market manipulation charges under sections 1041A(c) and 1041B(1)(a) of the Corporations Act following an ASIC investigation into his trading in contracts for difference (CFDs) and shares in 2013 and 2014 (BD: Aug 28, 2017).

In a media release, ASIC said that Mr Boitcheff pleaded guilty to charges of carrying out 117 transactions in CFDs relating to Anteo shares which had the effect of creating an artificial increased price for Anteo shares between January 3, 2013 and October 28, 2013 and carrying out four transactions in Anteo CFDs and shares that had the effect of creating a false or misleading appearance of active trading in Anteo shares between May 8, 2013 and January 7, 2014.

ASIC Commissioner Cathie Armour said that "any form of market manipulation undermines the integrity of our financial markets and creates an uneven playing field".

"It is important that markets operate fairly and that people who attempt to deliberately interfere in that process are brought to account," Ms Armour said.

Anteo fell 0.1 cents or 6.7 percent to 1.4 cents.

RESAPP HEALTH

Resapp has told the ASX that it is aware of information that had not been announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 50.0 percent from 12 cents on April 3 to 18 cents on April 9, 2018 and noted a significant increase in trading volume.

Resapp said it was aware of information relating to its clinical studies that had not yet been announced to the market, as well as a planned presentation at the Techknow Invest Conference, in Sydney today and Melbourne on April 12, which had "historically generated keen interest in the company".

Resapp fell 2.5 cents or 14.3 percent to 15 cents with 15.1 million shares traded.

RESAPP HEALTH

Resapp says it has "excellent preliminary results" for its clinical proof-of-concept studies in obstructive sleep apnoea.

Resapp said it had developed new machine-learning algorithms to measure the severity of obstructive sleep apnoea from a patient's overnight breathing and snoring sounds recorded using a smartphone on a bedside table.

The company said preliminary results from the study achieved 86 percent sensitivity, or the rate of correct positive detections, and 83 percent specificity, or the rate of correct negative detections, with results obtained from a cohort of 731 patients, 62 percent of which were male.

Resapp said it was working with the Perth-based Cardio Respiratory Sleep's Dr Philip Currie and Dr Ivan Ling to recruit patients at Perth's Hollywood Private Hospital and Park Private Hospital.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says that Health Canada has approved its Penthrox methoxyflurane inhaled analgesic.
Medical Developments said that the marketing authorization was its third approval in the last four weeks, after Germany and Estonia approved Penthrox.
Medical Developments chief executive officer John Sharman said Penthrox would be distributed in Canada through the New York-based Purdue Pharma.
Medical Developments was up six cents or 0.9 percent to $7.03.

TELIX PHARMACEUTICALS

Telix says its Kyzeo Imaging joint venture will provide its 68Ga-PSMA-11 diagnostic kit to Endocyte for its phase III trial of 177Lu-PSMA-617 for prostate cancer.
Telix said the 68 Gallium-labelled prostate-specific membrane antigen 11 (68Ga-PSMA-11) 11 kit was developed by its US division and was marketed by its Kyzeo joint venture with the Liege, Belgium-based Advanced Nuclear Medicine Ingredients (ANMI) SA.
The company said that Kyzeo had agreed to grant the West Lafayette, Indiana-based Endocyte access to the drug master file for a 68Ga-PSMA-11 kit and provide sufficient kits on a collaborative basis.
Telix said this would provide Endocyte an additional kit-based option for the labelling of PSMA-11, one of the imaging modalities used for patient selection in the 750-patient, phase III 'Vision' trial of patients with progressive prostate specific membrane antigen-positive metastatic castration-resistant prostate cancer, who had received at least one novel androgen axis drug and at least one taxane regimen.
The company said that Endocyte would provide Kyzeo access to the necessary pharmacovigilance and product safety data related to the kit for incorporation into Kyzeo's regulatory filings with the US Food and Drug Administration for the 68Ga-PSMA-11 prostate imaging agent.
Telix said that the agreement included standard pharmacovigilance and product safety reporting provisions.
Telix was up 4.5 cents or 7.8 percent to 62.5 cents.

DORSAVI

Dorsavi says Perth's Curtin University will use its Vimove technology to manage a 490-patient trial for low back pain treatment.
Dorsavi said the study would be led by Curtin University's School of Physiotherapy and Exercise Science and use the Vimove2 technology to combine clinician and patient applications with its US Food and Drug Administration-cleared wearable mini-sensors.
The company said the project included the use of 100 Vimove2 devices and was worth more than $205,000.
Dorsavi said Curtin University was a National Health and Medical Research Council grant for the project, which included the purchase of the Vimove2 equipment.
Dorsavi chief executive officer Dr Andrew Ronchi said the company was "pleased to see that Dorsavi's technology continues to be recognized as a leading and objective bio-feedback measure in clinical setting and applications".
"In particular, this trial will use our technology to help assess low back pain treatments, an increasing major public issue, given there are an estimated 540 million people globally affected by back pain at any one time," Dr Ronchi said.
Dorsavi was unchanged at 18 cents.

RESPIRI

Respiri says it has raised $3.0 million at eight cents a share a 14.0 percent discount to the 15-day volume weighted average price to April 4, 2018.
Respiri said the raising would provide the "financial capacity to progress to the launch [of its at-home monitoring device] Airsonea Gen II, which is scheduled for early 2019".
The company said that the Melbourne-based Fawkner Capital was the lead manager to the placement.
Respiri fell 0.1 cents or 1.1 percent to 8.9 cents with 1.7 million shares traded.

MMJ PHYTOTECH

MMJ says it has invested $1 million for a 16.7 percent ownership in Cannabis Access, a Biologics Research Institute-owned "online portal" for medical cannabis in Australia.
MMJ said Cannabis Access operated the portal for doctors and pharmacists to describe and access medical marijuana available in Australia and the conditions for which they were best-suited to treat.
The company said Cannabis Access had 500 Australian doctors and pharmacists signed up to the online portal.
MMJ chief executive officer Jason Conroy said "there are significant challenges for Australian patients who want to access medical cannabis and doctors who want to prescribe it".
"Cannabis Access is strongly positioned to address these challenges and we are proud to support them," Mr Conroy said.
MMJ said the online portal could be located at www.cannabisaccess.com.au.
MMJ fell half a cent or 1.4 percent to 36 cents.

G (GEVA) MEDICAL INNOVATIONS

G Medical has requested a trading halt "pending an announcement responding to an analyst report".
Trading will resume on April 12, 2018 or on an earlier announcement.
G Medical was up 1.5 cents or 4.7 percent to 33.5 cents prior to the halt.

SUDA PHARMACEUTICALS

Suda says its chairman Michael Stewart has resigned "for personal reasons".
Suda said Mr Stewart had been under "tremendous pressure after his wife unexpectedly suffered a spinal stroke that has left her wheelchair bound".
The company said Mr Stewart had advised in a statement that he needed to turn his full attention to supporting his wife as they both come to terms with what has occurred, and that this personal issue would take strict priority for him.
Suda said Mr Stewart would continue to provide the company with support and offered to provide consultation on specific issues as required.
The company said it had begun a search for a new chairperson and in the interim Suda chief executive officer Stephen Carter had been appointed executive chairman.
Mr Carter said that "Mike Stewart made a substantial contribution to Suda during his tenure as chairman".
"However, we understand the tragic circumstances that have instigated his resignation and we offer Mike and his wife, Lyn, our best wishes for the future," Mr Carter said.
Suda fell 0.1 cents or 7.1 percent to 1.3 cents with 6.5 million shares traded.

PHARMAUST

Pharmaust says its wholly-owned subsidiary Epichem has appointed co-founder Dr Wayne Best as chairman and Dr Martine Keenan as chief executive officer.

Pharmaust said that Dr Best would continue as an independent non-executive director of Pharmaust.

The company said that Dr Keenan was previously Epichem's head of discovery services.

Pharmaust said that Dr Keenan had "built an international reputation for drug discovery in infectious diseases with over 35 scientific publications and patents" and managed large multi-national collaborative drug discovery projects that have been core to Epichem's success in synthetic and medicinal chemistry.

The company said that Dr Keenan had about 20 years' experience in drug discovery in academia and industry and held a Doctor of Philosophy from King's College in London.

Pharmaust said that Dr Keenan would be paid a base salary of $140,000 a year with a potential bonus of up to $30,000 a year pending after-tax profit milestones.

The company said that Dr Best would be paid a chairman's fee of $9,000 a year and $30,000 a year as a director of Pharmaust.

Pharmaust was up 0.1 cents or 1.9 percent to 5.4 cents.