Biotech Daily

Monday January 29, 2018

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: BENITEC UP 11%; GENETIC SIGS DOWN 9%**

*** STUDY BACKS PATRYS PAT-DX1-NP FOR TUMORS, METASTASES IN MICE**

*** CORRECTION: ACTINOGEN MEDICAL**

*** AUSTRIA APPROVES MEDICAL DEVELOPMENTS PENTHROX FOR PAIN**

*** VISIONEERING: 'NATURALVUE DECREASES MYOPIA PROGRESSION'**

*** BOTANIX CLAIMS SYNTHETIC CANNABIDIOL BTX1503 ACNE SUCCESS**

*** MMJ REQUESTS 'MATERIAL INVESTMENT' TRADING HALT**

*** PRESCIENT 'ON-TRACK' FOLLOWING PTX-200 CLINICAL HOLDS**

*** CELLMID H1 RECEIPTS UP 6% TO $2.4m**

*** ONCOSIL HAS LESS THAN TWO QUARTERS CASH**

*** PROTEOMICS GRANTED JAPANESE PATENT**

*** US ALLOWS RACE BISANTRENE PATENT**

*** ESENSE ISRAELI BOARD SPILL MEETING**

*** CLINUVEL APPOINTS DR KAREN AGERSBORG US DIRECTOR**

MARKET REPORT

The Australian stock market was up 0.42 percent on Monday January 29, 2018, with the ASX200 up 25.4 points to 6,075.4 points. Fifteen of the Biotech Daily Top 40 stocks were up, 20 fell, three traded unchanged and two were untraded. All three Big Caps were up.

Benitec was the best, up 2.5 cents or 11.1 percent to 25 cents with 416,681 shares traded. Dimerix climbed 4.2 percent; Impedimed and Medical Developments were up more than three percent; Actinogen, Clinuvel, LBT, Resmed, Viralytics and Volpara rose more than two percent; Avita, Cochlear, CSL, Orthocell, Pharmaxis and Sirtex were up more than one percent; with Mesoblast and Starpharma up by less than one percent.

Genetic Signatures led the falls, down three cents or 9.4 percent to 29 cents with 94,614 shares traded. Osprey fell 9.2 percent; Uscom lost six percent; Bionomics, Factor Therapeutics, Immutep (Prima) and Neuren fell more than four percent; Acrux, Admedus, Psivida, Oncosil and Universal Biosensors lost more than three percent; Compumedics and Polynovo shed more than two percent; Airxpanders, Ellex, Optiscan and Telix were down more than one percent; with Nanosonics and Pro Medicus down by less than one percent.

PATRYS

Patrys says Yale University mouse studies shows that PAT-DX1-NP are specifically delivered to breast cancer tissue and axillary lymph node metastases.
Patrys said the study, conducted by Dr James Hansen and Dr Jiangbing Zhou, found mice with xenograft triple negative breast cancer tumors showed higher localization of PAT-DX1-NP, conjugating PAT-DX1 with nanoparticles, at tumor sites when compared to unconjugated nanoparticles.
The company said mice with breast cancer tumors were treated with free nanoparticles or PAT-DX1-NP.
Patrys said that both nanocarriers were loaded with a staining agent that allowed them to be tracked in the mice by an imaging system.
The company said the results showed improved targeting of primary tumors, which was consistent with previous studies in breast and glioblastoma tumors.
Patrys said the study also showed PAT-DX1-NP's ability to localize to axillary, or armpit, lymph node metastases, the most common site to which breast cancer spreads.
The company said that because PAT-DX1 targeted the extracellular DNA released by dying cancer cells it was not surprised that the nanoparticles had the potential to target non-primary cancerous cells such as lymph nodes and distant metastases, but this was the first animal study to produce direct evidence.
Patrys said the results suggested that targeted delivery of treatments could allow lower doses of chemotherapies.
Patrys chief executive officer Dr James Campbell said the study "confirmed [PAT-DX1-NP] could be used to localize a range of different tumors" and the company would "expand the PAT-DX1-NP program to trial the delivery of nanoparticles embedded with chemotherapeutics in coming months".
"An eventual therapeutic could have broad utility, treating both primary and secondary tumors, potentially before the latter had even been identified," Dr Campbell said. "There is now support for diagnostic imaging applications for the PAT-DX1 technology, which we have foreseen in our patent strategy and intellectual property filings."
Patrys was up 0.2 cents or 9.5 percent to 2.3 cents with 101.7 million shares traded.

ACTINOGEN MEDICAL

Last Thursday's edition, said that Actinogen would "release safety and efficacy data for the first 50 patients in April and June … [and] the blinded results are not expected to be statistically significant".
Actinogen chief executive officer Dr Bill Ketelbey told Biotech Daily that by June 2018 the data safety monitoring board would review the unblinded data from the first 50 of the 156 evaluable patients, and results blinded to the company could not be statistically analyzed.
Biotech Daily apologizes unreservedly for the error which was made by a sub-editor who thought he was still on holidays - and now is, permanently.
Actinogen was up 0.1 cents or 2.5 percent to 4.1 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says that its inhaled Penthrox methoxyflurane analgesic has been approved for sale in Austria.
Medical Developments chief executive officer John Sharman said he expected the remaining 19 European countries to issue marketing authorizations in coming months.
Medical Developments was up 24 cents or 3.1 percent to $8.00.

VISIONEERING TECHNOLOGIES

Visioneering says that 91-patient retrospective data shows that Naturalvue multifocal one-day contact lenses decrease the progression of paediatric myopia by 91 percent.

Visioneering said that three presentations on myopia, or short-sightedness, at the Global Specialty Lens Symposium in Las Vegas January 25 to 28, 2018 covered “nearly 100 children across 12 different practice locations” and showed that an average of 91 percent of children experienced a decrease in their myopic progression.

The company said that the average decrease of progression rate was 97 percent and the most frequent finding was a 100 percent decrease in myopic progression on an annualized basis.

Visioneering said that on average, 72 percent of children showed a complete halting of progression of myopic refractive error changes.

Visioneering chief executive officer Stephen Snowdy told Biotech Daily that “the lenses not only correct the myopic vision, so that the patient can see clearly, but also reduces or halts the worsening of the myopia over time”.

The company said that Dr Brett O’Connor presented ‘Myopia Management with a Unique Extended Depth of Focus Contact Lens: A Case Series Analysis’ summarized data from 27 children aged eight to 16 years and showed that 96 percent of the children “had a decrease in the amount of their refractive error change on an annualized basis, with an average decrease of 103%, indicating many children [39 percent] demonstrated regression of some portion of their prior myopic refractive error change”.

Visioneering said that Dr Thomas Aller presented ‘In Myopia Progression Before and After Fitting with Naturalvue Multifocal Contact Lenses: A Case Series Analysis’ on 32 patients aged seven to 22 years before and after switching to Naturalvue with a 93 percent reduction of myopic refractive error change on an annualized basis with 41 percent demonstrating a regression of some portion of their prior myopic refractive error change.

The company said that data on a subset of 15 children who had been previously prescribed an intervention for myopia prior to using the Naturalvue had their myopic progression reduced from -0.49 dioptres a year to -0.07 dioptres with Naturalvue, an 86 percent decrease in myopic progression as compared to the prior interventions.

Visioneering said that Dr Sally Dillehay presented ‘Case Series Analysis of Myopic Progression Control with a Unique Extended Depth of Focus Multifocal Contact Lens’ which reviewed 32 children at 10 practices and found that 98 percent showed an average 96 percent reduction in myopic refractive error on an annualized basis, with 81 percent of children having a complete halt or regression of myopic refractive error changes.

The company said that 8.4 percent of children in the three groups continued to progress in myopia, with 28.8 percent demonstrating a reduction in the amount of their myopic refractive error.

Visioneering said the data at 6-months of wear were “highly consistent with 12, 18 and 24-month data, indicating that these changes in the progression of the myopic refractive errors is holding over the long term”.

Visioneering chief medical officer and head of clinical, medical and regulatory affairs Dr Dillehay said “the fact that there was actually some regression in the amount of the myopic refractive error is especially promising and consistent with our prior findings in an animal [chick] model, where the lens design was shown to fully reverse approximately 10.00 dioptre of myopia in that animal model”.

“We look forward to continuing to examine the impact of the Naturalvue multifocal lens design on myopia and observed changes in refractive error and axial length,” Dr Dillehay said.

Visioneering was up half a cent or 1.1 percent to 46.5 cents.

BOTANIX PHARMACEUTICALS

Botanix says its 21-patient, phase Ib trial of topical synthetic cannabidiol BTX1503 shows the compound is safe and effective at reducing acne after four weeks of treatment.
Botanix said the trial was designed to evaluate the safety, tolerability and pharmacology of BTX1503 for acne and achieved all program goals.
The company said that BTX1503 had "an excellent safety profile" and was "very effective" at reducing the number of inflammatory acne lesions, or papules and pustules, and non-inflammatory acne lesions, or white heads and black heads, after four weeks of treatment.
Botanix said that patients were treated for 28 days, assessed for safety, tolerability, and efficacy at day-28 and at a follow-up visit on day-35.
The company said that inflammatory lesions decreased by an average 47 percent by day-28 and said that was a "significant reduction … greater than any other [US Food and Drug Administration] approved topical acne product, for which data is available after four weeks of treatment".
Botanix said that the comparative figures were 42 percent for Allergan's Epiduo and 38 percent for Galderma's Aczone.
The company said the study showed that patients maintained an average 45 percent reduction in inflammatory lesions at the follow up on day-35, after a week of no treatment.
Botanix said that non-inflammatory lesions were traditionally slower to respond to treatment and decreased in the patient study by 5.4 percent at day-28 and showed a larger decrease of 22.5 percent at day-35.
The company said that there were no serious adverse events and no subjects discontinued the study due to an adverse event.
Botanix executive director Matt Callahan said the results "show that BTX1503 is potentially a very safe and highly effective therapy for the treatment of acne".
"The acne market has suffered from a distinct lack of innovative products for more than 20 years and BTX1503 offers an exciting new alternative to the millions of patients with acne," Mr Callahan said.
"We are extremely excited about the data generated from only 4 weeks of treatment," Mr Callahan said.
"The large reduction in inflammatory acne lesions observed after this short treatment period, is better than the leading topically applied products currently available on the market," Mr Callahan said.
"We expect to see even greater reductions in acne lesions and continued safety when treatment with BTX1503 is extended out to 12 weeks," Mr Callahan said.
Botanix said it planned to take BTX1503 to a 400-patient, phase II, randomized, double-blind, controlled, dose ranging acne study in North America and Australia by July 2018.
Mr Callahan said the results provided "strong evidence of the role synthetic cannabidiol can play to positively impact inflammation".
"Inflammation plays a key role in atopic dermatitis and a number of other skin diseases that Botanix aims to target, so these results also help to validate and support the broader potential of the Botanix product portfolio," Mr Callahan said.
Botanix was up three cents or 23.1 percent to 16 cents with 48.0 million shares traded.

MMJ PHYTOTECH

MMJ has requested a trading halt "pending an announcement regarding a material investment".
Trading will resume on January 31, 2018 or on an earlier announcement.
MMJ last traded at 50.5 cents.

PRESCIENT

Prescient says with all clinical holds removed from its PTX-200 trials it expects final results from its phase Ib trial with paclitaxel for breast cancer by April 2018.

Prescient paused recruitment to three trials following the death of the last of 29 patients in the breast cancer trial, which resumed in December, following its phase Ib/II trial for acute myeloid leukaemia resuming in September and the phase Ib trial for ovarian cancer resuming in November (BD: May 29, Sep 4, Nov 6, Dec 11, 2017).

Today, the company said that the clinical hold on the breast cancer trial "was lifted without amendment to the dosing schedule, meaning that this trial can effectively recommence from where it stopped" in phase II, with five patients qualifying for data analysis.

Prescient said that based on final phase Ib results, it would modify the protocol to strengthen the phase II analysis, in particular stratifying patients based on their hormone receptor status to observe responses in different breast cancer sub-types.

The company said that phase II recruitment would recommence "around the middle of 2018".

Prescient said its trial of PTX-200 with cytarabine for acute myeloid leukaemia had recommenced, with five patients recruited to the second dosing cohort of 35mg/m2 and the phase Ib component "on-track to complete recruitment around mid-2018".

The company said it had amended the protocol for the phase Ib ovarian cancer trial to aid flexibility in carboplatin dosing and submitted the proposal to the US Food and Drug Administration for review, with the trial expected to be completed by the end of 2018.

Prescient chief executive officer Steven Yatomi-Clarke said that at the time of the clinical hold the company was "under budget and either ahead of schedule or on schedule in each of our trials".

"Accordingly, Prescient is well placed to minimize delays," Mr Yatomi-Clarke said.

Prescient fell 0.2 cents or 2.9 percent to 6.7 cents.

CELLMID

Cellmid says receipts from customers for the six months to December 31, 2017 increased 6.1 percent to $2,432,000 compared to the previous corresponding period.

In its Appendix 4C quarterly report Cellmid said that it received $1,421,000 in receipts from customers for the six months compared to $1,410,000 in the six months to December 31, 2016.

The company said that sales of its FGF5 inhibitor hair growth and anti-aging hair care products was $2,025,451 for the six months to December 31, 2017, "an increase of 115 percent from the same period last year".

Cellmid said that "a significant proportion of the payments" in relation to the sales would be received by April 2018.

Cellmid fell one cent or two percent to 49 cents.

ONCOSIL MEDICAL

Oncosil says its net operating cash burn for the three months to December 31, 2017 was $3,326,000 with cash at the end of the quarter of $5,188,000.

Oncosil said it expected to spend a further $3,150,000 in the three months to March 31, 2018 and it received a $600,000 Federal Government Tax Incentive earlier this month (BD: Jan 21, 2018).

Oncosil fell half a cent or 3.45 percent to 14 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has been granted a patent in Japan for its Promarkerd diagnostic and prognostic diabetic kidney disease test.
Proteomics said the patent, entitled 'Biomarkers Associated with Pre-Diabetes, Diabetes and Diabetes Related Conditions' would provide intellectual property coverage until September 20, 2031.
The company said the patent had been granted in Australia, China, Russia, Singapore and the US, with patents pending in Brazil, Canada, Indonesia, India and Europe.
Proteomics said it was in discussions with potential licencing partners in the US, Mexico, Japan, Australia, China and Europe.
Proteomics fell 2.5 cents or 7.6 percent to 30.5 cents.

RACE ONCOLOGY

Race says it has been allowed a patent relating to the use of Bisantrene for refractory or relapsed leukaemias, as well as breast cancer, lymphoma and other cancers
Race said that the patent, entitled 'Combinatorial Methods to Improve the Therapeutic Benefit of Bisantrene and Analogs and Derivatives Thereof' would provide intellectual property protection 2034 in the US.
The company said the patent was one of two Bisantrene patents filed in the US, Europe and five other countries, with the US being the first to allow this patent while still examining the second.
Race fell one cent or two percent to 49 cents.

ESENSE-LAB

Esense says it has received a request under Israeli Companies Law calling for a meeting to remove directors Haim Cohen, Eran Gilboa and Ilan Saad.
Esense said the notice was received under section 63(b)(2) of the Israeli Companies Law 5759-1999, from shareholders Romfal Sifat Pty Ltd, Buzz Capital Pty Ltd and Attollo Investments Pty Ltd, requesting the removal of chief executive officer Mr Cohen and directors Eran Gilboa and Ilan Saad as well as the appointment as directors of current chairman Dr Brendan de Kauwe, if he is not re-elected at the annual general meeting, as well as MMJ Phytotech chief executive officer Andreas Gedeon and Faldi Ismail.
Esense said it was considering its obligations in connection with the notice.
Esense fell 3.5 cents or 13.7 percent to 22 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says Dr Karen Agersborg has been appointed as a US-based director.
Clinuvel said Dr Agersborg was a clinical endocrinologist at Pennsylvania's Reading Hospital and had worked at the East Norriton, Pennsylvania Suburban Hospital and Pennsylvania's Chestnut Hill Hospital and previously worked in sales and distribution at Wyeth Pharmaceuticals.
The company said Dr Agersborg held a Doctorate of Osteopathic Medicine from the Philadelphia College of Osteopathic Medicine.
Clinuvel was up 21 cents or 2.4 percent to $8.86.