Biotech Daily

Wednesday November 29, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: AVITA UP 17%; ACTINOGEN DOWN 10%**

*** VOLPARA LAUNCHES ENTERPRISE LIVE FOR QUALITY, RISK SOFTWARE**

*** ACTINOGEN RAISES $5.3m**

*** RHINOMED RAISES $3.6m**

*** LBT APAS PASSES ST VINCENT'S HOSPITAL LAB ASSESSMENT**

*** FACTOR THERAPEUTICS VF001 LEG ULCER TRIAL 'HALF RECRUITED'**

*** ZELDA MARIJUANA INSOMNIA TRIAL**

*** CRESO JOINT VENTURE FOR MARIJUANA BEER**

*** NOXOPHARM: 'NYX-104 PROTECTS BRAIN POST-STROKE IN MICE'**

*** UP TO 32% OF SUDA AGM OPPOSE DIRECTOR OPTIONS**

*** LBT 20% OPPOSE PLACEMENT CAPACITY, 19% REMUNERATION REPORT**

*** ADHERIUM 18% OPPOSE DIRECTOR JEREMY CURNOCK COOK**

*** GENERA TAKES 'PARTNERING AGREEMENT' HALT TO SUSPENSION**

*** SUDA APPOINTS BIOSCIENCE MANAGERS DAVID PHILLIPS ADVISOR**

*** RECCE REPLACES CO SEC, CFO PETER WILLIAMS**

*** AVITA MOVES AUSTRALIA, EUROPE OFFICES**

MARKET REPORT

The Australian stock market climbed 0.45 percent on Wednesday November 29, 2017, with the ASX200 up 26.8 points to 6,011.1 points. Eighteen of the Biotech Daily Top 40 stocks were up, 15 fell, five traded unchanged and two were untraded.

Avita was best, up 0.9 cents or 17.3 percent to 6.1 cents with 4.4 million shares traded. Benitec climbed 10 percent; Compumedics was up 9.1 percent; Factor Therapeutics improved 6.4 percent; ITL, Pharmaxis and Starpharma were up four percent or more; Bionomics, Genetic Signatures, LBT, Mesoblast and Oncosil were up more than three percent; Cellmid and Sirtex rose more than two percent; Osprey and Prana were up more than one percent; with Impedimed, Pro Medicus and Resmed up less than one percent.

Actinogen led the falls, down 0.5 cents or 10.4 percent to 4.3 cents with 7.3 million shares traded. Psivida and Viralytics lost more than seven percent; Living Cell fell 6.25 percent; Dimerix and Volpara fell more than five percent; Admedus and Airxpanders were down more than three percent; Ellex and Neuren shed more than two percent; with Clinuvel, Cochlear, Nanosonics, Opthea, Polynovo and Reva down more than one percent.

VOLPARA HEALTH TECHNOLOGIES

Volpara says it has launched two new products to maintain consistent quality in breast screening and help identify women who may be at high risk of developing cancer.
Volpara said it launched the Enterprise Live mammography quality control tool and Volpara Risk software to identify high risk women at the Radiological Society of North America meeting in Chicago, from November 26 to December 1, 2017.
The company published a media release but did not file the announcement to the ASX.
Volpara said the Enterprise Live system was “designed to help technologists acquire consistent, high quality mammograms … [calculating] the patient positioning score, dose and compression pressure for each image within 30 seconds of acquisition”.
The company said that, pending regulatory approval, Enterprise Live would provide quality data to operators before the patient left the room, reducing technical recalls and retakes and promoting mammography quality.
Volpara said that the majority of breast cancer patients had minimal family history of breast cancer, so reliance on family history pathways did not capture all high-risk women, but its Risk software helped identify women who might be at increased risk of developing breast cancer, irrespective of family history and might benefit from a full risk assessment.
Volpara said the Risk software ranked each mammogram according to the magnitude of the mammographic density relative to the woman's age and breast size.
The company said the software helped identify additional women who could be directed to the facility’s high-risk clinic and potentially to supplemental screening.
Volpara fell 3.5 cents or 5.3 percent to 62 cents.

ACTINOGEN MEDICAL

Actinogen says it has raised $5,280,000 at four cents a share in an “oversubscribed” placement to sophisticated private investors.
Actinogen said the proceeds would be used for the completion of its phase II study of Xanamen for Alzheimer’s disease, with results expected by July 2019.
The company said that an interim data analysis would be conducted on the first 50 patients, with results available by July 2018, one year earlier than the full study results.
Actinogen said the shares would be issued in two tranches, with the second tranche of 40.5 million shares subject to shareholder approval.
The company said placement shares would come with one free option for every two new shares, exercisable at six cents each by March 31, 2019.
Actinogen said that all existing shareholders would be issued two free options for every 15 shares held at the record date of December 7, 2017 on the same terms.
The company said Forrest Capital was the lead manager to the placement.
Actinogen fell half a cent or 10.4 percent to 4.3 cents with 7.3 million shares traded.

RHINOMED

Rhinomed says it has raised $3.6 million at 15 cents a share in a placement to institutional and sophisticated private investors.
Rhinomed said proceeds would be used to drive growth of the company’s Mute snoring and sleeping device and provide working capital.
The company said that chairman Ron Dewhurst and chief executive officer Michael Johnson would participate in the placement, pending shareholder approval.
Rhinomed said that Bell Potter Securities managed the placement.
Rhinomed was unchanged at 15 cents.

LBT INNOVATIONS

LBT says an independent evaluation by Melbourne's St Vincent's Hospital confirms the utility of its APAS automated plate assessment system in a clinical setting.

LBT said that additional efficiencies were gained at the specimen processing step, which was expected to be representative of other laboratories.

The company said that more than 3,000 urine samples were automatically read and interpreted by the APAS Independence instrument, in its first in-situ installation.

LBT said that the US Food and Drug Administration cleared APAS was an artificial intelligence technology for the automated imaging, image analysis, interpretation and reporting of growth on microbiology plates after incubation, improving the diagnostic efficiency of microbiology laboratories and enabling faster reporting of infectious diseases.

The company said that the six-week placement at St Vincent's Hospital enabled the evaluation of the instrument's performance in a diagnostic pathology laboratory.

LBT chief executive officer Brent Barnes said it was "pleasing the instrument performed successfully in a real world setting in this global first trial".

"The evaluation of the instrument provides clear validation that the foundational technology works and the instrument does deliver efficiencies in a laboratory," Mr Barnes said.

LBT said that St Vincent's Hospital microbiology laboratory trial reported that the instrument worked and performance targets were met, laboratory efficiencies were observed, installation was easy with no special requirements as it was wheeled into a laboratory and plugged-in, the APAS had a high level of user engagement and the user interface was intuitive and easy to use.

LBT scientific director Dr Steven Giglio worked with St Vincent's Hospital in setting up the evaluation and said the instrument "performed as expected during the evaluation and was successful in triaging the negative plates out of the workflow, allowing microbiologists to focus on positive plates only".

"In addition, the APAS Independence facilitated significant upstream benefits in specimen processing, realizing further efficiencies from the introduction of this instrument," Dr Giglio said.

"A significant amount of data has been generated which will form the basis for several scientific presentations and publications to disseminate these findings to the scientific community," Dr Giglio said.

LBT was up one cent or 3.85 percent to 27 cents.

FACTOR THERAPEUTICS

Factor Therapeutics says it has passed the recruitment half-way mark with 84 patients randomized in its 168-patient, phase II trial of VF001 for venous leg ulcers.

Factor Therapeutics chief executive officer Dr Ros Wilson said the trial was "on-target to complete recruitment [by July] of 2018.

"Recruitment is accelerating thanks to our active management strategy and as our social media campaign comes fully on-line and we are particularly pleased to see the spread of enrolment across our sites," Dr Wilson said.

Factor Therapeutics chair Dr Cherrell Hirst said that venous leg ulcers were "a critical burden for patients and health care providers worldwide".

"Completing this trial is a key goal for Factor Therapeutics and we are excited to pass this important milestone," Dr Hirst said.

Factor Therapeutics was up 0.3 cents or 6.4 percent to five cents with 2.1 million shares traded.

ZELDA THERAPEUTICS

Zelda says it has regulatory approval for a 24-patient, phase IIa trial of medicinal marijuana for chronic insomnia.

Zelda said the trial would be at the University of Western Australia Centre for Sleep Science directed by Prof Peter Eastwood.

The company said that US and Chile patient data showed “anecdotal evidence of benefit from medicinal cannabis when used to treat insomnia”.

Zelda said that it worked with the University of Western Australia research team “to develop a rigorous research trial protocol to study the clinical efficacy of its insomnia formulations”.

The company said the trial would target a sample population with symptoms of chronic insomnia, including difficulty falling and staying asleep on a long-term basis.

Zelda said the randomized, placebo-controlled, cross-over study design would compare its medicinal cannabis formulation with a placebo formulation.

The company said the cannabis formulation were being manufactured by the Netherlands-based Eurofins Sinensis.

Zelda said the trial would begin by April 2018, with recruitment expected to start shortly, and preliminary results expected by October 2018.

Zelda executive chairman Harry Karelis said the regulatory and ethics approvals were “a very exciting milestone for Zelda”.

“We have been meticulously working our way through the regulatory framework to ensure we achieve all necessary approvals,” Mr Karelis said.

Prof Eastwood said that “population-based data show that about one third of adults have regular difficulty getting to sleep or staying asleep”.

“We are very excited to be conducting this trial sponsored by Zelda Therapeutics, which will be an Australian first for investigating medical cannabis as a potential treatment for sleep disorders due to insomnia,” Prof Eastwood said.

Zelda was up two cents or 17.4 percent to 13.5 cents with 40.7 million shares traded.

CRESO PHARMA

Creso says it has a letter of intent with LGC Capital and Baltic Beer Co to combine marijuana with alcoholic and non-alcoholic beverages.

The company said an unnamed joint venture company comprising of Creso chief executive officer Dr Miri Halperin Wernli, the Montreal, Quebec-based LGC Capital chief executive officer John McMullen and the London, England-based Baltic Beer Co director Alex Klaos would oversee operations and product development.

Creso said that research had begun in Switzerland, Estonia and the UK to develop an alcoholic and a non-alcoholic beer containing terpenes, or essential oils, that mimic the terpenes from cannabis.

The company said the terpenes would give the beer the characteristic odor, fragrance, taste and feel of cannabis but would not contain tetrahydrocannabinol or any other cannabinoids and would not be subject to regulatory restrictions.

Creso said the first batches were expected by May 2018 and commercial sales were expected by July 2018.

Creso fell four cents or 3.2 percent to $1.21 cents with 4.9 million shares traded.

NOXOPHARM

Noxopharm says its NYX-104 has shown a significant level of neuroprotection in mouse models of human stroke.

Noxopharm said data from the trial would be presented today at the Cerebral Vascular Biology International Conference in Melbourne.

The company previously said that in a collaboration with the University of New South Wales it had identified NYX-104 as a potential candidate to treat excito-toxicity in-vitro, while this data was in-vivo (BD: Nov 3, 2017).

Noxopharm said the data confirmed that NYX-104 inhibited excito-toxicity in-vivo, "confirming the ability of the drug to cross the blood brain barrier".

Noxopharm chief executive officer Dr Graham Kelly said the results indicated that Noxopharm could "proceed with confidence to develop NYX-104 as a neuroprotective drug for the treatment for excitotoxicity".

"We will be focusing in the first instance on using the drug to protect the brain from stroke injury," Dr Kelly said.

"NYX-104 cannot stop stroke from occurring, but by administering the drug once stroke has occurred, the aim will be to limit the extent of the second wave of brain damage," Dr Kelly said.

"Less damage should mean less loss of function, shorter recovery periods and greater likelihood of making a full recovery," Dr Kelly said

Dr Kelly said that "given the potential role of excito-toxicity in anything that kills brain cells ranging from physical trauma through to degenerative disease [such as Alzheimer's disease and Parkinson's disease], a successful neuro-protectant has significant community use".

Dr Kelly said that Noxopharm subsidiary Nyrada Inc intended to take NYX-104 to a human clinical trial in 2019.

Noxopharm climbed seven cents or 8.3 percent to 91 cents.

SUDA PHARMACEUTICALS

Suda's annual general meeting passed all resolutions, but voted up to 32 percent dissent against the issue of 19,000,000 director options (BD: Nov 1, 2017).

Suda said the strongest opposing vote was against the issue of 4,000,000 options to chief financial officer Joseph Ohayon, opposed by 88,353,338 votes (31.7%), with 190,570,648 votes (68.3%) in favor.

The company said the issue of 7,500,000 options each to chief executive officer Stephen Carter and director Michael Stewart were opposed with similar dissent.

Suda's most recent Appendix 3B new issue announcement said that Suda had 1,221,425,388 shares on issue, meaning that the votes against Mr Ohayon's options amounted to 7.2 percent of the company, sufficient to requisition extraordinary general meetings.

The company said approvals for the issue of convertible notes to directors and related parties, the ratification of the prior issue of 75,000,000 shares, the issue of 10 million options to RM Capital, the adoption of an employee share plan and the re-election of director Mr Ohayon were passed by wider margins.

Suda said the remuneration report was passed by more than 253.7 million votes (82.9%) in favor and 37.3 million votes (17.1%) against, while the change of name to Suda Pharmaceuticals was passed overwhelmingly, as was the adoption of a tax-exempt plan.

Suda fell 0.1 cents or 5.6 percent to 1.7 cents with 2.85 million shares traded.

LBT INNOVATIONS

LBT says its annual general meeting passed all votes but voted with dissent against the placement capacity, remuneration report and director Stephen Mathwin.
LBT said that 10 approval of the 10 percent placement capacity was opposed by 8,485,964 votes (20.4%) and supported by 33,045,305 votes (79.6%).
The company said the remuneration report was passed by 19,687,185 votes (80.9%), with 4,656,362 votes (19.1%) against.
LBT said that Mr Mathwin was re-elected with 33.9 million in favor and 7.75 million votes against, with Matthew Michalewicz and Dr Glenn Haifer elected by a wider margin.
The company said the issue of options to Dr Haifer was opposed by 5.5 million votes and supported by 28.6 million votes, with options for Mr Michalewicz passed by a narrower margin.
The company's most recent Appendix 3B new issue announcement said that LBT had 141,896,121 shares on issue, meaning that the vote against the 10 percent placement capacity amounted to 5.98 percent of the company, sufficient to requisition extraordinary general meetings.

ADHERIUM

Adherium says its annual general meeting passed all resolutions, but with up to 18 percent opposition to the re-election of director Jeremy Curnock Cook.
Adherium said that 13,353,727 votes (17.67%) opposed Mr Curnock Cook's re-election, with 62,106,217 votes (82.16%) in favor and 126,000 (0.17%) at the proxy's discretion.
The company said that 7.3 percent opposed the remuneration report with the election of chief executive officer Arik Anderson as a directors and the 10 placement capacity passed overwhelmingly.
Adherium's most recent Appendix 3B said the company had 174,881,264 shares on issue meaning that the opposition to Mr Curnock Cook amounted to 7.6 percent of the total shares on issue, sufficient to requisition extraordinary general meetings.
Adherium was up 0.8 cents or 11.1 percent to eight cents.

GENERA BIOSYSTEMS

Genera has requested a voluntary suspension to follow the trading halt requested on November 27, "pending an announcement … regarding [an] … agreement … in relation to its Ampasand molecular diagnostic testing menu" (BD: Nov 27, 2017).
Genera last traded at 20.5 cents.

SUDA PHARMACEUTICALS

Suda says it has appointed David Phillips as an advisor to the board of directors, effective from December 1, 2017.
Suda said that Mr Phillips had more than 30 years in the healthcare industry including 14 years in sales and marketing with Glaxo Wellcome, Cephalon, Oxford Molecular Group PLC and eight years with Glaxosmithkline corporate venture fund SR One, as well as 12 years as chief business officer at Argenta Discovery, the Automation Partnership and Biofocus PLC.
The company said that Mr Phillips was currently a senior investment manager at Melbourne's Bioscience Managers.

RECCE PHARMACEUTICALS

Recce says Alistair McKeough and Justin Reynolds have replaced Peter Williams as company secretary and chief financial officer, respectively.
Recce said that Mr McKeough worked for the Sydney-based law firm Whittens & McKeough Pty Ltd and would be company secretary, effective from November 29, 2017.
The company said that Mr Reynolds worked for accountants Pitcher Partners in Sydney.
Recce thanked Mr Williams for his contributions.
Recce fell one cent or 5.4 percent to 17.5 cents.

AVITA MEDICAL

Avita says it is relocating its Perth Office to the East Coast of Australia and its London office to an as yet undecided location in the European Union.
Avita has an office in Valencia California, where chief executive officer Dr Mike Perry is based with other senior staff members.
“The decision to transition these two office locations is part of our global commercialization strategy, which includes re-aligning our priorities and resources in advance of our anticipated approval of Recell in the US,” Dr Perry said.
Avita was up 0.9 cents or 17.3 percent to 6.1 cents with 4.4 million shares traded.