Biotech Daily

Wednesday October 4, 2017

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: AVITA UP 14%; DIMERIX DOWN 12.5%**

*** REDHILL BEKINDA (RHB-102) MEETS PHASE II IBD TRIAL ENDPOINTS**

*** MEDIBIO SIGNS 2nd MAYO CLINIC DEAL FOR PSYCH TRIALS**

*** OPTISCAN $1m PLACEMENT TAKES TOTAL TO $3.5m**

*** FDA EASES RESTRICTIONS ON AVITA RECELL BURNS PROTOCOL**

*** POLYNOVO APPOINTS AMI ISRAEL DISTRIBUTOR**

*** MICRO-X DELIVERS 1st NANO-X-RAY TO CARESTREAM**

*** ALCIDION SIGNS 3-YEAR, $389k MONASH HEALTH DEAL**

*** COURT OKAYS MEDICAL AUSTRALIA, ICU SCHEME BOOKLET, MEETING**

*** NEUROTECH TELLS 112% ASX AWARE QUERY: 'WE NEEDED TIME'**

*** RESAPP 2nd STRIKE BOARD SPILL AGM**

*** NOXOPHARM SPIN-OUT NYRADA EGM**

*** CRESO TO RELEASE 2m ESCROW SHARES**

*** CLINUVEL LOSES DIRECTOR ELIE ISHAG**

MARKET REPORT

The Australian stock market fell 0.87 percent on Wednesday October 4, 2017 with the ASX200 down 49.3 points to 5,652.1 points. Eighteen of the Biotech Daily Top 40 stocks were up, 12 fell, six traded unchanged and four were untraded.

Avita was the best, up one cent or 14.1 percent to 8.1 cents with 8.2 million shares traded. Prima climbed 8.7 percent; Benitec, Genetic Signatures and Mesoblast rose more than six percent; Cellmid, Living Cell and Oncosil were up more than four percent; Impedimed and LBT were up more than three percent; Acrux and Compumedics rose more than two percent; Cochlear, ITL, Sirtex and Starpharma were up more than one percent; with Medical Developments, Nanosonics and Viralytics up by less than one percent.

Dimerix led the falls, down 0.1 cents or 12.5 percent to 0.7 cents with 2.5 million shares traded. Actinogen lost 5.2 percent; Clinuvel fell 4.8 percent; Reva, Resmed, Universal Biosensors and Uscom shed more than two percent; Factor Therapeutics, Neuren, Osprey, Polynovo and Volpara were down more than one percent; with CSL and Pro Medicus down by less than one percent.

REDHILL BIOPHARMA

Redhill says its 126-patient, phase II study of 12mg Bekinda (RHB-102) for diarrhoea-predominant irritable bowel syndrome met its primary endpoint of stool consistency.
Redhill said the randomized, double-blind, placebo-controlled, phase II trial showed improvement in 54.7 percent of Bekinda-treated patients compared to 35.3 percent for placebo ($p = 0.05$).
The company said its trial showed a 19.4 percent absolute difference compared to the reported outcomes from studies of Xifaxan, or rifaximin, which achieved a 10.5 percent absolute difference and Viberzi, or eluxadoline, with a 13.5 percent absolute difference.
Redhill said that although the study was not statistically powered for the secondary endpoints, Bekinda improved the overall worst abdominal pain response rate by 11.5 percent compared to placebo ($p = 0.28$), which compared favorably with Xifaxan 550mg (9.0%) and Viberzi 100mg (5.0%).
The company said Bekinda was safe and well-tolerated with no serious adverse events.
Redhill said that irritable bowel syndrome was one of the most common gastro-intestinal disorders, affecting an estimated 30 million Americans, of which more than 50 percent were cases of diarrhoea-predominant irritable bowel syndrome (IBS-D).
Redhill said it intended to pursue phase III studies with Bekinda and planned to meet with the US Food and Drug Administration by early 2018 to discuss the path to US approval.
Redhill medical director Dr Terry Plasse said the study “demonstrated that Bekinda 12mg could be an effective treatment for patients suffering from IBS-D”.
In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).
On the Nasdaq, Redhill fell $US1.42 or 13.14 percent to $US9.39 ($A11.94) with 738,978 shares traded.

MEDIBIO

Medibio says it has signed a five-year master clinical trial agreement with the Rochester Minnesota-based Mayo Clinic.
Medibio said that the agreement provided for multiple trials involving the use of one or more of its products as well as assisting the development of future products.
The company said that research could be conducted at either a single or multiple US locations to explore future indications for the screening, diagnosis, monitoring, and management of mental health disorders.
Medibio chief executive officer Jack Cosentino said the company was “excited to sign our second agreement with Mayo Clinic and to move forward jointly on clinical trials to further expand our technology into additional areas of mental health”.
In May, Medibio said it had a three-year development agreement with the Mayo Clinic for its assessment and management of mental illness technology (BD: May 10, 2017).
“The clinical trials expected to come from this agreement will further solidify Medibio’s research and approach on effectively screening, as well as differentiating types of mental illness, and monitoring drug therapy effectiveness and adherence for mental health patients,” Mr Cosentino said.
Mr Cosentino said the Mayo Clinic provided psychiatry and psychology services and was “an innovator and leader” of products that had become the standard-of-care.
Medibio said that mental health was “the largest clinical problem today with an estimated 350 million people word-wide suffering from depression and [was] the leading cause of disability in the US”.
Medibio fell 3.5 cents or 8.05 percent to 40 cents with 1.2 million shares traded.

OPTISCAN IMAGING LIMITED

Optiscan says it has completed a $1,000,000 placement at eight cents a share taking the total raised with its underwritten share plan to $3.5 million (BD: Sep 27, 2017).
Optiscan said that the share plan was underwritten by Paterson Securities.
The company said the funds would be used to meet orders from partner Carl Zeiss Meditech, meet the expected product demand for its Viewnvivo systems, fund sales and marketing costs as well as research and development activities and working capital.
Optiscan was unchanged at 9.7 cents.

AVITA MEDICAL

Avita says the US Food and Drug Administration has simplified its Recell continued access protocol and increased the number of investigational sites from eight to 15.
Avita said the FDA allowed a supplement to its investigational device exemption for its Recell spray-on skin autologous cell harvesting device for burn injuries.
The company said that treatment with the Recell device under continued access was under a complex protocol requiring a randomized comparison between two distinct areas of burn injury, with one area treated using conventional skin grafts and one area treated with more expanded autografts applied in combination with Recell.
Avita said the new protocol allowed for the use of spray-on skin with expanded, or meshed, autografts without requiring the randomized comparison to a conventional graft.
The company said the continued access protocol was complementary to the compassionate use protocol, with participants' burn injuries allowed to range from five to 50 percent of total body surface area, whereas the compassionate use was limited to the most extensive of burn injuries.
The Winston-Salem North Carolina-based Wake Forest Baptist Medical Centre burns director Dr James Holmes said that the previous protocol was a concern but "the new continued access protocol, without a comparison, allows us to continue use of Recell with more focus on what's best for the patient".
Avita said the continued access provision allowed doctors to access a medical device while the premarket approval application was under review if there was a public need for the device and preliminary evidence that the device was likely to be effective, with no significant safety concerns.
Avita clinical development head Andy Quick said that continued access "allows Avita to further develop our understanding of the integration of Recell into the US burn surgeons' armamentarium".
Avita was up one cent or 14.1 percent to 8.1 cents with 8.2 million shares traded.

POLYNOVO

Polynovo says it has signed the Tel Aviv-based AMI Medical Technologies as Israel distributor for its Novosorb biodegradable temporizing matrix for wounds.
Polynovo said that AMI was a medical distributor and the two companies had engaged with Israeli surgeons to assess the market potential and the suitability of a distributor.
The company said that the Israel market held "significant promise as it is an innovative biomedical market that demonstrates early adoption of leading technologies".
Polynovo chief executive officer Paul Brennan said that "Polynovo's entry into a sophisticated medical market such as Israel is an exciting opportunity to work with leading surgeons who are seen as key opinion leaders on the global stage".
Polynovo fell half a cent or 1.8 percent to 27.5 cents.

MICRO-X

Micro-X says its distributor Carestream Health has formally accepted the first production unit of its DRX Revolution Nano carbon nano-tube-powered x-ray units.
Micro-X said that the hand-over ceremony at its facility at Tonsley in Adelaide was attended by the South Australia Premier Jay Weatherill.
The Rochester New York-based Carestream Health head of x-ray products Charlie Hicks said that his company was “a market leader in introducing innovative technologies to address the needs of healthcare providers and we are proud of our partnership with Micro-X to make this another successful Carestream product”.
Micro-X managing-director Peter Rowland said the event was “a huge milestone”.
“These are the first production-standard units, fully capable and approved for clinical use to be built and now delivered to Carestream,” Mr Rowland said.
Micro-X said the event was attended by supply-chain partners as well as representatives from Federal, State and local Government, Health Industries SA who were able to see the DRX Revolution Nano production line assembly in operation.
Micro-X was up two cents or 5.3 percent to 40 cents.

ALCIDION GROUP

Alcidion says it has signed a three-year deal worth more than $389,000 with Monash Health for its mobile telephone task management product.
Alcidion said that the contract provided an option for two additional one-year extensions, which would increase the contract value to $500,000.
The company said Monash Health was a major public hospital network including Monash Medical Centre, Monash Children’s Hospital, Dandenong Hospital, Casey Hospital and it managed Moorabbin Hospital, Kingston Centre and a range of community-based sites and services.
Alcidion said that its Miya Smartpage product would provide Monash Health with out-of-hours clinical task management, delivering two-way instant communications between clinical staff to increase productivity and improve patient care.
In August, Alcidion said the Miya Smartpage Clinical software system was expected to be operational by the end of 2017 (BD: Aug 31, 2017).
Alcidion chief executive officer Ray Blight said the company was “delighted to be working with Monash Health to help them deliver efficient and effective healthcare to the Southern Metropolitan Melbourne community”.
“Our Miya Smartpage … will provide their clinical staff with communication and workflow tools that make it faster and simpler for them to do their job and continue to deliver the very best patient care during a hospital’s most vulnerable time, the night,”Mr Blight said.
Alcidion was up 0.2 cents or 4.1 percent to 5.1 cents.

MEDICAL AUSTRALIA

Medical Australia says the Federal Court of Australia has approved the scheme booklet for the takeover by ICU Medical (BD: Aug 10, 2017).
Medical Australia said the Court ordered a shareholder meeting to vote on the scheme.
The company said that the implementation of the scheme was subject to the satisfaction or waiver as applicable of certain conditions, including shareholder approval in respect of the scheme and approval by the Court.
Medical Australia said the scheme meeting would be held on November 15, 2017.
Medical Australia was untraded at 8.3 cents.

NEUROTECH INTERNATIONAL

Neurotech says it first knew of trial results on Friday September 22, that they were "incredible" or "outstanding" the next day and needed time for the announcement.

The ASX noted the change in the company's share price from a closing price of 16.5 cents on September 22 to an opening price of 36.5 cents on September 27 an increase of 112.12 percent and an increase in trading volumes on the same day.

Last week, Neurotech said that Bedfordshire Centre for Mental Health Research's Prof Frederick Carrick delivered the "incredible preliminary results" of a Mente Autism study at the Cambridge International Conference on Mental Health (BD: Sep 27, 2017).

Today the company said it knew the presentation was on Friday September 22 but it required time to make the announcement, requesting a trading halt on September 25 until the announcement on September 27.

Neurotech replied to the ASX 'aware' query that at 10.55pm (AEST) on Saturday, September 23, it was presented with two quoted paragraphs set out in the announcement, portions of which were paraphrased in the announcement, which was when it first became aware of the information in the presentation.

The company said it was "not aware of the preliminary findings prior to the presentation" and "the information delivered at the presentation is not understood to contain new price sensitive material on its own".

The company said the time to prepare the announcement was increased due to a director being located in the UK and it was required to liaise with Prof Carrick to ensure the announcement "accurately reflected the results … and was not misleading or deceptive".

Neurotech said it made its trading halt request to the ASX on Sunday September 24.

Neurotech fell two cents or 8.2 percent to 22.5 cents with 1.5 million shares traded.

RESAPP HEALTH

Resapp's annual general meeting will vote on the remuneration report, a potential second strike board spill, placement capacity and the re-election of directors.

Last year, Resapp narrowly earned a remuneration report first strike with the annual general meeting voting 26.4 percent against the report (BD: Nov 3, 2016).

Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company with a vote of 25 percent or more against the remuneration report in two successive meetings is required to vote on a board spill.

Resapp said that shareholders would vote on the re-election of director Dr Roger Aston and the approval of the 10 percent placement facility.

The meeting will be held at the Four Seasons Hotel, 199 George Street, Sydney on November 3, 2017 at 10.30am (AEDT).

Resapp was up half a cent or 7.1 percent to 7.5 cents with 2.6 million shares traded.

NOXOPHARM

Noxopharm says it will hold an extraordinary general meeting to approve transactions relating to the establishment of Nyrada Inc.

Last week, Noxopharm said it had formed the subsidiary Nyrada Inc to develop pre-clinical, non-oncology drug intellectual property, spun out from assets owned by Noxopharm and director Dr Ian Dixon (BD: Sep 25, 2017).

Today, the company said that the meeting would be held at its offices at Suite 3, Level 4, 828 Pacific Highway, Gordon, Sydney on November 6, 2017 at 10am (AEDT).

Noxopharm was up 1.5 cents or 4.6 percent to 34 cents.

CRESO PHARMA

Creso says that 1,000,000 shares and 1,000,000 ‘performance’ shares held by partner Hemp Industries SRO will be released from escrow on October 13, 2017.
According to the company’s most recent Appendix 3B new issue statement Creso would have 68,245,502 shares available for trading after the release with a further 23,200,001shares held in escrow.
Creso fell 1.5 cents or 2.8 percent to 52 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says that non-executive director Elie Ishag will not stand for re-election at the annual general meeting, but will continue to serve on the board until the meeting.
Clinuvel said that Mr Ishag was a shareholder for 12 years and joined the board in February 2011.
The company said it was undertaking a search for a new director.
Clinuvel fell 34 cents or 4.8 percent to $6.70.