Biotech Daily

Friday November 18, 2016

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: NEUREN UP 13%, ONCOSIL DOWN 9%**

*** ADHERIUM STUDY: 'SMARTINHALER IMPROVES ASTHMA OUTCOMES'**

*** COCHLEAR HAS COMPLEX US COURT OF APPEAL PATENT DECISION**

*** MEDIBIO EXPECTS TO RAISE $13.5m**

*** UP TO 40% OF POLYNOVO OPPOSE 33% DIRECTORS FEE POOL HIKE**

*** VOLPARA REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** ZELDA RELISTS NOV 22 FOR MARIJUANA FOR INSOMNIA, ACNE, CANCER**

*** BVF PARTNERS, MARK LAMPERT REDUCE TO 13.6% IN VIRALYTICS**

MARKET REPORT

The Australian stock market was up 0.39 percent on Friday November 18, 2016 with the ASX200 up 20.9 points to 5,359.4 points.

Eleven of the Biotech Daily Top 40 stocks were up, 12 fell, 13 traded unchanged and four were untraded.

Neuren was the best for the second day in a row, up 0.8 cents or 12.7 percent to 7.1 cents with 2.3 million shares traded.

Benitec climbed 10.0 percent; Anteo was up 6.1 percent; Dimerix improved 5.9 percent; Opthea and Mesoblast were up more than four percent; Resmed was up 3.1 percent; Living Cell rose 2.1 percent; Orthocell and Pharmaxis were up more than one percent; with Nanosonics and Sirtex up by less than one percent.

Oncosil led the falls, down one cent or 8.7 percent to 10.5 cents with 751,853 shares traded.

Osprey, Prana and Viralytics lost more than six percent; Cellmid fell 3.2 percent; Bionomics and Impedimed shed more than two percent; Airxpanders and Polynovo were down more than one percent; with Clinuvel, Cochlear, CSL, Cyclopharm and Starpharma down by less than one percent.

ADHERIUM

Adherium says an independent study shows its Smartinhaler improves outcomes and medication adherence in children with asthma, reducing days off school and doctor visits.

Adherium said the independent, randomized, controlled trial of its Smartinhaler medication adherence tool showed that improvements in clinical outcomes, medication adherence in children increased over time, particularly at nine and 12 months.

The article, 'STAAR: a randomised controlled trial of electronic adherence monitoring with reminder alarms and feedback to improve clinical outcomes for children with asthma' was published in the British Medical Journal's 'Thorax', with an abstract at: http://thorax.bmj.com/content/early/2016/11/04/thoraxjnl-2015-208171.abstract.

Adherium said that study of children with poorly controlled asthma, showed a significant reduction in hospital admissions over the course of 12 months as well as substantial other health and quality of life benefits.

The company said that the 12-month study at the UK's Sheffield Children's Hospital was led by the University of Sheffield's Dr Robert Morton and colleagues.

Adherium said the aim of the study was to assess whether introducing digital adherence monitoring into routine practice using the Smartinhaler, which attached to standard asthma puffers, could improve clinical outcomes in children with poorly controlled asthma.

Dr Morton said the study "provides good evidence that adherence monitoring with feedback can significantly improve clinical outcomes when used in the management of children with poorly controlled asthma".

"The benefits of the intervention were sustained over a prolonged period of time, and we have shown that this approach can be effectively administered in a clinically practical way," Dr Morton said.

Adherium said that 77 of the 90 recruited children completed the Staar study, with 38 children in the intervention group using the Smartinhaler adherence monitor with medication reminders and feedback in the clinic and 39 children received usual care as part of a control group.

The company said that adherence to prescribed medication averaged 70 percent in the intervention group, compared to 49 percent in the intervention group ($p < 0.001$) with nearly half of the children in the Smartinhaler group maintaining average adherence rates of more the 80 percent over the 12 months.

Adherium said that the adherence improvement was associated with significant reduction in asthma exacerbations, which could be life threatening.

The company said that the need for a course of oral steroids, a marker of severe exacerbations, was 53 percent more common in the usual care group compared to the intervention group ($p = 0.008$).

Adherium said that the hospitalization rate was five times greater in the control group compared to the Smartinhaler intervention group ($p < 0.001$), approximating to the prevention of 12 hospitalizations in one year among the children in the intervention group, making a cost-saving argument for using Smartinhaler in routine practice.

The company said that the clinical benefits observed within the intervention group increased compared to the usual care group, particularly at nine and 12 months, with the intervention group requiring fewer courses of oral steroids, hospital admissions, days off school and doctor or emergency department visits.

Adherium chief executive officer Garth Sutherland said that the "significant increase in medication adherence and reduction in asthma exacerbations combined with a reduction in children being admitted to hospital is proof of the clinical effectiveness of our Smartinhaler technology".

Adherium was unchanged at 34 cents.

COCHLEAR

Cochlear says a US Federal Court of Appeals has ruled that it infringed two of four claims across two patents.

Cochlear said that the US Court of Appeals for the Federal Circuit, in Washington, DC heard the appeal against the judgement in the patent infringement lawsuit by the Alfred E Mann Foundation for Scientific Research and Advanced Bionics LLC against Cochlear and its US subsidiary Cochlear Americas.

The company said that in January 2014 a jury found that Cochlear infringed four claims across two patents, the infringement was “willful” and awarded $US131,216,325 in damages.

Cochlear said that on April 1, 2015, a judge in the US District Court in Los Angeles, California held that three of the four patent claims were invalid and Cochlear’s infringement of the remaining claim was not “willful”.

The company said that the judge overturned the damages awarded because three of the four claims were held to be invalid.

Cochlear said that on April 21, 2015, the Court entered judgement on liability and stayed a new trial on damages pending the outcome of the appeals by all parties.

The company said that the Court of Appeals affirmed the judgement on infringement, affirmed the judgement on the invalidity of one patent and reversed the judgement of invalidity as to one claim in the other patent.

Cochlear did not specify whether the two invalid claims were both in one of the two patents, or whether both patents had one valid and one invalid claim.

Cochlear said that the Court of Appeals remanded the issue of damages and willfulness of infringement of two claims in the one remaining patent at issue to the District Court, implying that one patent had two valid claims and the other patent had two invalid claims.

The company said that “the nature of the US legal process is such that the timeframe and final future outcomes are still uncertain”.

Cochlear said that a provision was expensed in the six months to December 13, 2013 for this dispute and provision of $21.3 million was disclosed at note 5.5 on page 74 in the 93-page 2016 annual report.

The company said that as the patents had expired, the trial judgement and the Court of Appeals decision would not disrupt its US business or customers.

Cochlear fell 56 cents or 0.5 percent to $119.27 with 200,054 shares traded.

MEDIBIO

Medibio says it commitments to raise $13.5 million at 40 cents a share in two tranches “to fast-track the clinical pathway of the business”.

Medibio said that the placement was oversubscribed from domestic and foreign institutions with Fidelity International, on behalf of various accounts, joining the register and becoming a major shareholder.

The company said that Hunter Capital Advisors and Foster Stockbroking were joint lead managers for the capital raising with Cove Capital acting as broker.

Medibio said the funds were for studies to provide data to support US Food and Drug Administration and Conformité Européenne (CE) mark filings, associated regulatory work, treatment efficacy for depression, gradations of depression and general anxiety disorder and allocate a budget to its workplace mental health product for commercialization as well as a consumer mental health product and the flexibility to retire a $US2.5 million convertible note, which would leave the company debt free.

Medibio fell two cents or 4.3 percent to 45 cents.

POLYNOVO

Polynovo's annual general meeting voted up to 40.4 percent dissent against a 33.3 percent increase in the directors remuneration pool for $300,000 a year to $400,000.
Polynovo said that 74,893,255 shares (54.7%) supported the non-executive directors increase with 55,316,925 votes (40.4%) against and 6,593,690 votes at the proxy's discretion.
The company said that resolutions to elect director Leon Hoare and the issue opf employee options were passed by a wider margin with more than 90.9 million votes in favor and more than 35.1 million votes against, while the remuneration report and the re-election of chairman David Williams and director Max Johnston were passed overwhelmingly.
The company's most recent Appendix 3B new issue announcement said that Polynovo had 562,232,115 shares on issue, meaning that the votes against the increase to the directors remuneration pool amounted to 9.8 percent of the company, sufficient to requisition extraordinary general meetings.
Polynovo fell half a cent or 1.8 percent to 27 cents.

VOLPARA HEALTH TECHNOLOGIES

Volpara has requested a trading halt "pending the release of an announcement to the market in relation to a proposed equity capital raising".
Trading will resume on November 22, 2016 or on an earlier announcement.
Volpara last traded at 83.5 cents.

ZELDA THERAPEUTICS (FORMERLY GLENEAGLE GOLD)

Zelda says it will relist on the ASX under the code ZLD todevelop sublingual and topical marijuana treatments for insomnia, acne and glioblastoma (BD: Aug 24, 2016).
On Wednesday, Zelda said it had raised the $4 million maximum allowed under its prospectus offering at 2.5 cents a share (BD: Nov 16, 2016).
Zelda said that the funds were to continue with pre-clinical research and development activities, fund human clinical trials and expand the management and advisory team.
Zelda, then Gleneagle Gold, last traded at 2.5 cents post-consolidation.

VIRALYTICS

BVF Partners and Mark Lampert say they have reduced their substantial holding in Viralytics from 34,604,778 shares (14.58%) to 32,568,321 shares (13.55%).
The San Francisco, California-based BVF Partners and Mr Lampert said they sold the shares between July 18 and November 11, 2016 in 46 trades with the single largest the disposal 448,186 shares for $412,956 or 99.1 cents share.
Last year, BVF acquired 11,032, 845 shares when Viralytics was trading around 60 to 65 cents and in 2014, BVF acquired 2,000,000 shares on-market for $600,000 or 30 cents a share (BD: Nov 28, 2014; Jan 25, 2016)
Viralytics fell 8.5 cents or 6.7 percent to $1.19.