Biotech Daily

Thursday May 4, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ONCOSIL UP 9%, ADMEDUS DOWN 18%**

*** ADMEDUS COR-1 FOR HSV-2 'SAFE, INTERESTING TRENDS'**

*** CANN OPENS UP 117% TO GROW MARIJUANA**

*** AUSCANN REQUESTS 'UPDATE' TRADING HALT**

*** CHINA ISSUES DORSAVI 'BODY ORIENTATION' PATENT**

*** MAYNE TELLS ASX: BURIED SALES WARNING 'NOT MATERIAL'**

*** INVESTORS MUTUAL TAKES 5% OF MAYNE PHARMA**

*** ANALYTICA PERICOACH PELVIC FLOOR EXERCISE PROGRAM**

*** IQ3 TO RELEASE 80m ESCROW SHARES**

MARKET REPORT

The Australian stock market fell 0.27 percent on Thursday May 4, 2017 with the ASX200 down 15.9 points to 5,876.4 points.

Eight of the Biotech Daily Top 40 stocks were up, 17 fell, 11 traded unchanged and four were untraded.

Oncosil was the best, up one cent or 8.7 percent to 12.5 cents, with 941,793 shares traded.

Pharmaxis, Prima and Reva climbed more than three percent; Actinogen rose 2.4 percent; Orthocell improved 1.2 percent; with Clinuvel, CSL, ITL and Resmed up by less than one percent.

Admedus led the falls, down seven cents or 18.4 percent to 31 cents with 2.6 million shares traded, followed by Mesoblast down 14.3 percent to $2.69 with 2.3 million shares traded and Benitec down 10.5 percent to 17 cents with 72,010 shares traded.

Compumedics lost 7.3 percent; Cyclopharm, Factor Therapeutics, IDT, Medical Developments, Prana and Universal Biosensors were down more than three percent; Sirtex and Starpharma shed two percent or more; Acrux, Neuren, Opthea and Osprey were down more than one percent; with Cochlear and Ellex down less than one percent.

ADMEDUS

Admedus says its phase IIa trial of COR-1 for herpes simplex virus-2 has shown safety and “interesting trends” in reducing viral shedding, viral lesions and further outbreaks.

In a brief ‘no questions’ webinar, discussing all the company’s programs, Admedus chief executive officer Wayne Paterson said the results made it “an extremely positive study” despite the lack of statistical efficacy on any of the secondary or exploratory outcomes.

Mr Paterson said that COR-1 met the safety and tolerability measures with eight withdrawals not related to the vaccine, no serious adverse events and one moderate adverse event.

Mr Paterson said that the patients were randomized to three cohorts, with the first receiving two 0.5mg sub-cutaneous injections per vaccination into each arm, with the second cohort receiving two 0.5mg sub-cutaneous injections into the left arm only and the third cohort receiving placebo.

The webinar presentation said that each patient received three vaccinations plus a booster after six months.

The presentation said that the secondary endpoint was to investigate COR-1 induction of an antigen specific response, with exploratory endpoints including viral shedding herpes lesion recurrence and immunological responses.

Mr Paterson said that lesion incidence in all groups was “similar”, there were no viral load differences, but there was a trend towards COR-1 for reducing outbreaks post-vaccination with 10 patients of 34 patients in the vaccine group (29.4%) experiencing no outbreaks, compared to one of 10 patients (10%) in the placebo group having no outbreaks post-vaccination.

Charts in the presentation showed that reductions in HSV-2 virus by 59.9 percent in the first cohort of 17 patients compared to a 2.2 percent fall for the five control patients.

But the chart showed a greater fall in HSV-2 virus in the second cohort arm for the five placebo patients (64.6%) compared to the 17 patients receiving COR-1 injections in the left arm only (47.4%).

The presentation showed an up to 50 percent T-cell response for the first COR-1 cohort, falling to 23.5 percent in the second cohort and no response for placebo patients, with responses falling from post-vaccination to post booster injection.

The presentations aid that the median time to recurrence was 6.6 months for the combined vaccine group, compared to 1.2 months for the placebo group.

Mr Paterson said that the company would take the drug to a larger phase IIb trial and investigate higher doses of the vaccine as well as analyze other intra-derma delivery methods and explore complementary approaches to improve immune responses.

Mr Paterson said that Admedus would begin a phase Ib human papillomavirus head and neck cancer trial “very soon” in combination with a checkpoint inhibitor

Mr Paterson said that an RNA therapeutic program using two of the company’s technologies, originally conducted with the Dublin, Ireland based Shire Pharmaceuticals had been sent to Rana Therapeutics and was continuing.

He said that the program was using lipid nanoparticle encapsulation and had shown antibody and T-cell responses.

The presentation said that the company planned animal studies this year for a model of a human papillomavirus cancer.

Mr Paterson said the company was reviewing all funding options and hoping to find external funds without the need for a capital raise.

The trial began in 2015 and last year Admedus said a 20-patient interim analysis showed safety, viral shedding but no benefit for new lesions (BD: Apr 10, 2015; Oct 19, 2016).

Admedus lost seven cents or 18.4 percent to 31 cents with 2.6 million shares traded.

CANN GROUP

Melbourne's Cann Group opened at 65 cents this morning, a 116.7 percent premium to its fully underwritten $13.5 million initial public offer at 30 cents a share.
Cann climbed to a high of 77 cents two minutes after opening at 11.15am traded around 60 cents for most of the day.
Cann said in its prospectus that the capital raising was underwritten by Cannacord Genuity and PAC Partners.
The company said in a presentation today that its chairman was Allan McCallum, the directors included music industry entrepreneur Philip Jacobsen, Doug Rathbone and Geoff Pearce, with Peter Crock as chief executive officer.
The company said that along with the 45,000,000 shares issued in the public offer, there were 53,473,336 existing shares, 2,700,000 shares for the underwriters in lieu of cash payment and a further 7,180,000 class B "performance" shares, giving a total of 108,353,336 shares.
In February, the then public unlisted Cann Group said it had the first Australian Office of Drug Control licence to grow medicinal cannabis ((BD: Feb 21, 2017).
Cann said the Federal Office of Drug Control research licence allowed it to cultivate cannabis and conduct research on the use of cannabis for medicinal purposes, and it had submitted an application for a cultivation licence which was expected in the near future.
The company said its research and development facilities had operated under an authority for low-tetrahydrocannabinol (low-THC) from the Victoria Government, authorizing cultivation of low-THC cannabis for research and non-therapeutic purposes.
Cann said the research program had focused on evaluating optimal conditions, processes and equipment for cultivating cannabis.
Cann said its objective was to be recognized as the leading developer and supplier of regulated medicinal cannabis in Australia.
Cann closed up 34.5 cents or 115.0 percent at 64.5 cents with 7.5 million shares traded.

AUSCANN GROUP

Auscann has requested a trading halt pending the "release of an announcement regarding an update to the Australian operations".
Trading will resume on May 8, 2017 or on an earlier announcement.
Auscann last traded up 1.5 cents or 2.65 percent at 58 cents.

DORSAVI

Dorsavi says China has issued its first patent covering its body orientation technology, entitled 'apparatus and method for classifying orientation of a body of a mammal'.
The company said the patent was described as a method for automatically detecting whether a person was standing, sitting, lying down or engaged in a dynamic activity.
Dorsavi is commercializing wearable body movement sensors and said the patent strengthened its "lead in accurately measuring movement and muscle activity".
"Understanding body orientation is an important component of assessing whether certain movements are associated with a high risk of causing an injury and is relevant for the clinical, the occupational health and safety and the sporting markets," Dorsavi said.
The company said that patent applications covering the intellectual property were undergoing review in other geographies.
Dorsavi did not say when it made the application or the duration of coverage.
Dorsavi fell one cent or 2.8 percent to 35 cents.

MAYNE PHARMA

Mayne Pharma has responded to an ASX “aware” query saying that a sales warning buried on page 107 of a 110 page investor presentation was “not material”.

The ASX said that on Monday, May 1, 2017 Mayne opened at $1.35, released the announcement at 12.06pm and closed down 10.7 percent at $1.205.

The ASX quoted Mayne slide 107 saying “Tougher generics pricing environment in 2H17 [the six months to June 30, 2017] which is expected to result in FY17 [the 12 months to June 30, 2017] Teva portfolio generic sales below original guidance”.

Mayne said the statement had been extracted from slide 107 without the benefit of the immediately following statement on the same page which said that the “Teva portfolio gross profit margins tracking ahead of 50 percent guidance and EBITDA [earnings before interest tax, depreciation and amortization] is broadly in line”.

Mayne said the statement read in context should have indicated to a reasonable person that EBITDA for the Teva portfolio was materially consistent with the guidance due to the better than expected gross profit margin.

The company said that even though sales were below original guidance it would not have a material effect on the price or value of its securities.

Mayne said that “to put this conclusion beyond doubt, a further clarification announcement was made on May 3, 2017 [SIC – it was actually May 2] which restated the above and confirmed that “Accordingly, the reduction in sales from the Teva portfolio is not expected to have a material impact on overall FY17 EBITDA”.

Mayne said that given that its answer to the first question was that the statement was not material, it responded to further awareness questions as “not applicable”.

The company said that it was in compliance with the Listing Rules.

The ASX said that Listing Rule 3.1 required a listed entity to give the ASX immediately any information concerning it that a reasonable person would expect to have a material effect on the price or value of the entity’s securities.

The ASX said that Section 4.14 of Guidance Note 8, stated that “ASX has experienced difficulties in the past with announcements that have been given a fairly innocuous header, such as ‘Chairman’s Address to AGM’, but have had market sensitive material embedded in them”.

ASX said it would ask entities to ensure that the header to such an announcement clearly identifies the fact that it contains market sensitive information, for example ‘Chairman’s Address to AGM and Buyback Announcement’, or, better still, that market sensitive announcements are made on a standalone basis and not embedded in other announcements that may not be market sensitive.

Mayne fell 1.5 cents or 1.2 percent to $1.19 with 13.1 million shares traded.

MAYNE PHARMA

The Sydney-based Investors Mutual says it has become a substantial holder in Mayne Pharma with 78,764,139 shares or 5.23 percent.

Investors Mutual said that it held the shares along with Aurora Investment Management which owned 20 percent of Investors Mutual and Pacific Current Group which owned 100 percent of Aurora Investment Management.

The company said that registered holders included Sandhurst Trustees, Citicorp Nominees, JP Morgan State Super, State Street and RBC Global Services Australia.

Investors Mutual said it acquired shares between February 1 and May 2, 2017 with the single largest purchase on May1, of 2,000,000 shares for $2,437,200 or $1.22 a share.

ANALYTICA

Analytica says it has released an exercise and behavior modification program designed to improve compliance and motivation for pelvic floor muscle rehabilitation.

Analytica said that exercise program enhanced its intra-vaginal Pericoach pelvic floor strengthening monitor which showed improvement in continence, quality of life and sexual function in a two-year controlled clinical trial.

The company said the program was an aggregate of clinical best practices for pelvic floor muscle exercise rehabilitation, insights from the Pericoach clinical trial, Pericoach post-market surveillance and behavioral data from anonymized user data, along with focus groups and surveys to understand women's perception of, and obstacles to, successful pelvic floor exercise and willingness to embrace structured programs.

Analytica said the 'Eight Week Challenge' was incorporated in the Pericoach mobile telephone application.

Analytica chief executive officer Geoff Daly said the exercise regime was "intended to drive home the key elements for successful conservative treatment of stress urinary incontinence, consistency and proper technique".

"All women know that they should be doing their pelvic floor exercise, but most don't do them properly or regularly enough to see the positive outcomes," Mr Daly said.

"So we've developed an easy, accessible, achievable plan for women to follow, stay motivated, and see results," Mr Daly said.

Analytica was untraded at 0.6 cents.

IQ3 CORP

IQ3 says that 80,000,000 shares and 191,667 options will be released from ASX escrow on May 18, 2017.

IQ3's May 15, 2015 pre-quotation disclosure document said that the company had 21,816,667 shares on issue, implying that after the release from escrow there would be 101,816,667 shares available for trading.

IQ3 was untraded at 29 cents.