Biotech Daily

Thursday March 9, 2017

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: OSPREY UP 7.5%, IDT DOWN 16%**

*** US APPROVES OSPREY DYEVERT PLUS**

*** PHOSPHAGENICS, INTEGRATED ANIMAL HEALTH 'CEASE ALL LICENCES'**

*** MAYNE BUYS TRANSDERMAL FENTANYL RIGHTS FROM PAR PHARMA**

*** ALLEGRA SHARE PLAN TO RAISE $1.2m**

*** OPTHEA: 'FDA CLEAR PATH FOR OPT-302 FOR WET AMD'**

*** MMJ TO GROW MARIJUANA ON 5HA OF COWICHAN TRIBES LAND**

*** ANGLO AUSTRALIAN CHRISTIAN FUND TAKES 19% OF CYCLOPHARM**

*** WINDARRI, HERZ INCREASE, DILUTED TO 8% OF BIOTECH CAPITAL**

*** CRYSTAL AMBER TAKES 40% OF GI DYNAMICS**

*** MACQUARIE GROUP PLAYING WITH MMJ TO 5%**

*** MAYNE APPOINTS NICK FREEMAN CFO, CO SEC**

MARKET REPORT

The Australian stock market fell 0.32 percent on Thursday March 9, 2017, with the ASX200 down 18.5 points to 5,741.2 points. Sixteen of the Biotech Daily Top 40 stocks were up, 11 fell, nine traded unchanged and four were untraded. All three Big Caps rose.

Osprey was the best, up three cents or 7.5 percent to 43 cents with 155,592 shares traded. Genetic Signatures climbed 7.1 percent; Polynovo was up 5.6 percent; Prana and Universal Biosensors improved more than four percent; Airxpanders and Starpharma were up more than three percent; Admedus, Clinuvel, Impedimed, Nanosonics, Orthocell and Sirtex rose more than two percent; Acrux and Medical Developments were up more than one percent; with Cochlear, CSL, Ellex and Resmed up by less than one percent.

IDT led the falls, down 2.5 cents or 16.1 percent to 13 cents with 1.1 million shares traded. Dimerix lost 14.3 percent; Oncosil was down six percent; Benitec shed 5.7 percent; Uscom fell 4.9 percent; Cellmid and Viralytics were down more than three percent; Opthea and Mesoblast shed more than two percent; with ITL down 1.1 percent.

OSPREY MEDICAL

Osprey says that the US Food and Drug Administration has granted FDA 510(k) clearance for its Dyevert Plus cardiac dye reduction system.
Osprey said that the Dyevert Plus platform augmented its existing technology with the capability to actively manage dye administration during coronary interventions.
The company said that the Dyevert Plus received Conformité Européenne (CE) mark approval last year (BD: Nov 2, 2016).
Osprey said that it had further validated its dye savings capabilities through market testing with physicians in Germany and Italy, which showed a 44 percent dye reduction, with "strong positive feedback on the utility of real-time contrast monitoring and ease-of-use".
The company said that recently-published industry guidelines had "a strong focus on dye management for kidney-impaired patients" which were the target of the Dyevert Plus.
Osprey said Dyevert Plus minimized contrast dose, gave contrast monitoring in real-time and informed physicians when kidney function limits were reached.
The Lubeck, Germany-based Heart Centre's Prof Steffen Desch said that the dye monitor was "a valuable feature, especially in a patient with impaired kidney function".
"You know exactly where you are at each point during an intervention," Prof Desch said.
Osprey was up three cents or 7.5 percent to 43 cents.

PHOSPHAGENICS

Phosphagenics says it has signed a settlement deed with Integrated Animal Health Pty Ltd "to cease all and any of their licences".
In 2015, Phosphagenics said it licenced its vitamin E tocopheryl phosphate mixture (TPM) technology to the Kansa City, Kansas-based Integrated Animal Health for animal nutrition products and the four-year licence allowed Integrated Animal Health, formerly based in Noosaville, Queensland, to use the technology in the manufacture and sale of the products in the UK and the Republic of Ireland (BD: Mar 25, 2015).
The company said at that time that Integrated Animal Health had a licence for the products in Australia and New Zealand through its subsidiary Mastitis Management Australia (BD: Dec 12, 2013).
Today, Phosphagenics said the details of the settlement were confidential but provided "a mutual solution to contractual issues that have arisen over the past year".
Phosphagenics fell 0.2 cents or 11.1 percent to 1.6 cents with 3.9 million shares traded.

MAYNE PHARMA GROUP

Mayne Pharma says it has acquired the rights to four doses of transdermal fentanyl from the Woodcliff Lake, New Jersey-based Par Pharmaceutical.
Mayne said that product was developed by the Menlo Park, California-based Corium, a specialty pharmaceutical company focused on the development and manufacture of transdermal and trans-mucosal delivery systems.
The company said that transdermal fentanyl was a generic equivalent to Duragesic for the management of pain in opioid-tolerant patients, severe enough to require daily treatment.
Mayne said it had assumed Par's manufacturing and supply agreement with Corium, acquired select inventory and the rights to market the product in the US from today.
The company said that it had the rights to 25mcg/hour, 50mcg/hour, 75 mcg/hour and 100 mcg/hour doses and market sales for the fentanyl patch were about $US560 million for the 12 months to December 31, 2016.
Mayne Pharma fell one cent or 0.75 percent to $1.325 with 6.3 million shares traded.

ALLEGRA ORTHOPAEDICS

Allegra says it hopes to raise up to $1,219,003 through a two-for-15 rights issue at 12.5 cents a share.
Allegra said that the record date would be March 14, the offer would open on March 17 and close on April 7, 2017.
Allegra said that the funds would be used to continue funding the Sr-HT-gahnite bone substitute project and increase its investment in surgical instrumentation and inventory to support the expansion of its surgeon base (BD: Apr 2, 2014; Jun 8, Sep 20, 2016).
Allegra was up 1.5 cents or 5.8 percent to 27.5 cents.

OPTHEA

Opthea says it has discussed its OPT-302 phase IIb trial and program for wet age-related macular degeneration with the US Food and Drug Administration.
Opthea said the type C meeting with the FDA's Division of Transplant and Ophthalmology Products provided guidance on the program for the OPT-302 vascular endothelial growth factor (VEGF) C and D trap therapy for wet age-related macular degeneration (AMD).
The company said that meeting covered the scope and design of the phase IIb trial, including patient eligibility criteria, statistical considerations including sample size, rationale for dose levels and guidance on trial endpoints to evaluate the safety and clinical efficacy of OPT-302.
Opthea chief executive officer Dr Megan Baldwin said the company was "very pleased with the FDA's thorough and positive feedback and its continued support to advance the OPT-302 program for back of the eye diseases such as wet AMD".
"The outcomes from this meeting provide a clear path forward to Opthea as we continue to execute our plan to initiate a larger, randomized and controlled phase IIb study in wet AMD patients in 2017," Dr Baldwin said.
The company said the meeting followed the completion of enrolment in the phase IIa dose-expansion cohorts of its on-going phase I/IIa trial.
Opthea said that the trial of wet AMD patients who were either treatment naïve or previously treated with anti-VEGF-A therapy, enrolled 20 patients in the phase I dose escalation and 31 patients in the phase IIa dose expansion.
The company said that 13 patients received OPT-302 by intra-vitreal injection either as a monotherapy, and 38 patients received OPT-302 in combination with the selective VEGF-A inhibitor Lucentis once a month for three months.
Opthea said that primary analysis from the phase I dose-escalation study showed safety and tolerability of OPT-302 as a monotherapy and in combination with Lucentis, with "encouraging signs of clinical activity of OPT-302 in the phase I study [suggesting] that combined administration of OPT-302 and Lucentis may lead to improved visual acuity and anatomical outcomes over Lucentis alone".
The company said it expected to reporting the outcome of the phase IIa dose expansion cohorts by the end of March 2017.
Opthea said wet AMD was the leading cause of blindness for people over the age of 50 in the US and Europe and was estimated to affect more than 1.5 million people worldwide and was increasing as the population aged, costing $US5 billion a year in the US alone.
The company said that OPT-302 was a soluble receptor that blocked VEGF-C and VEGF-D and used in combination with a VEGF-A inhibitor had the potential to improve vision in wet AMD patients by targeting mechanisms of sub-responsiveness to existing approved therapies for the disease.
Opthea fell two cents or 2.15 percent to 91 cents.

MMJ PHYTOTECH

MMJ says that Canada subsidiary United Greeneries has executed an agreement with the Cowichan Tribes for 13 acres (5.3 hectares) of land next to its Duncan facility (BD: 2015).
Last year, MMJ said it was negotiating with the Tribes for the land with the capacity to support up to 10 acres of greenhouse production space yielding about 25 tonnes a year of cannabis (BD: Aug 3,2016).
The company said at that time that the land was owned by the Tribes as private commercial property and it was clear, flat and had been vacant for several years, previously used for commercial greenhouse growing and would require little preparation (BD: Aug 3,2016).
Today, the company said that initially the land would support up to three acres of additional greenhouse production space, increasing production capacity to about 8,500kg (8.5 tonnes) of dried cannabis buds by the end of 2017.
MMJ said that the agreement provided for a potential joint venture with the Cowichan Tribes to expand to an additional 20 acres of greenhouse production space, increasing production capacity to about 50 tonnes a year, enabling it “to establish a first-mover advantage in the soon to be legalised Canadian recreational market” estimated to be worth about $C5 billion a year.
The company said the agreement met one of the final requirements for the release of funds from the $C25 million Harvest One placement with the reverse take-over expected to be completed by the of March (BD: February 23, 2017).
MMJ said that its first cannabis harvest was due by the end of March, 2017.
MMJ was up one cent or 2.6 percent to 39 cents with 15.5 million shares traded.

CYCLOPHARM

The London-based Anglo Australian Christian and Charitable Fund says it has become substantial in Cyclopharm with 11,517,600 shares or 19.28 percent.
Last month, the London-based Lloyds & Cassanove Investment Partners said it had sold its 10,568,470 Cyclopharm shares (17.69%) to the Anglo Australian Christian and Charitable Fund (BD: Feb 17, 2017).
Both companies give their addresses as 65 St Paul’s Churchyard, London.
In February, the Anglo Australian Christian and Charitable Fund said it bought 10,568,470 shares for $9,617,308 or 91.0 cents a share.
Today, the Anglo Australian Christian and Charitable Fund said it bought 11,517,600 shares for $9,941,016 or 86.3 cents a share.
Cyclopharm was untraded at 80 cents.

BIOTECH CAPITAL

Windarri Investments as trustee for the Herz Family Trust has increased its substantial holding in Biotech Capital from 10,000,000 shares to 10,100,000 shares.
The Windarri substantial shareholder notice said that the group was diluted from 9.21 percent to 7.95 percent in a share plan and placement at 11 cents a share which raised $2.4 million (BD: Feb 14, Mar 8, 2017).
Biotech Capital was unchanged at 12 cents.

GI DYNAMICS

The Crystal Amber Fund says it has increased its substantial shareholding in GI Dynamics from 216,047,954 shares (38.73%) to 221,810,862 shares (39.76%).
The London and St Peter Port, Guernsey Island-based Crystal Amber Fund said that between February 13 and March 8, 2017 it acquired 5,762,908 shares for $268,282 or 4.7 cents a share.
GI Dynamics was unchanged at four cents.

MMJ PHYTOTECH

The Sydney-based Macquarie Group says it has become substantial in MMJ, again, this time with 9,669,914 shares (5.05%).
Last week, the Macquarie Group said it has sold its shares to below the five percent substantial shareholder level in MMJ (BD: Feb 28, 2017).
Earlier in February, the Macquarie Group said it had become substantial in MMJ with 9,652,632 shares (5.04%) (BD: Feb 10, 2017).
Last week, the Macquarie substantial shareholder notice provided 15 pages of related companies and said it sold 2,000,000 shares at 35 cents a share on February 22, 2017.
Today, the Macquarie notice provided 15 pages of related companies and said it bought 508,840 shares at 28 and 29 cents a share on March 2 and 3, 2017.
Biotech Daily takes a very dim view of day-traders playing in the long-term life sciences sector, especially if they are involved in “shorting” stocks (BD: May 3, 2016).

MAYNE PHARMA GROUP

Mayne Pharma says it has appointed Nick Freeman as group chief financial officer and company secretary, effective from May 22, 2017.
Mayne said that Mr Freeman had 25 years’ experience as a chartered accountant and had worked in the retail, consumer goods, financial services, transport and oil and gas industries.
The company said that for the last 10 years, Mr Freeman “held a variety of chief financial officer roles” at the Australia and New Zealand (ANZ) Bank, most recently as chief financial officer for Australia the bank’s largest division and was formerly Qantas Airways group treasurer.
Mayne said that Mr Freeman held a Bachelor of Commerce from the University of Melbourne and a Graduate Diploma in Management from Monash University.