Biotech Daily

Tuesday July 6, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: OPTHEA UP 11%; POLYNOVO DOWN 9%**

*** US FAST TRACK STATUS FOR OPTHEA OPT-302 FOR WET AMD**

*** CARTHERICS SWAPS COLLABORATION FROM HUDSON TO ARMI, CCRM**

*** US FDA APPROVES IMMUTEP PHASE IIb TACTI-003 HNSCC TRIAL**

*** BIONOMICS BEGINS PHASE IIb BNC210 PTSD US TRIAL**

*** CRESO: RED LIGHT HOLLAND ORDERS $219k NETHERLANDS MARIJUANA**

*** FIL REDUCES TO 8% IN TELIX**

*** PLANET INNOVATION TAKES 27% OF LUMOS**

*** RPS DIAGNOSTICS TAKES 10% OF LUMOS**

*** PERENNIAL TAKES 8% OF LUMOS**

*** ACORN CAPITAL TAKES 6% OF LUMOS**

*** CEO FLETA SOLOMON INCREASES, DILUTED TO 8.7% OF LITTLE GREEN**

*** BIANCA RINEHART (HANCOCK TRUST) TAKES 11.5% OF LITTLE GREEN**

MARKET REPORT

The Australian stock market fell 0.73 percent on Tuesday July 6, 2021, with the ASX200 down 53.2 points to 7,261.8 points. Eight of the Biotech Daily Top 40 stocks were up, 24 fell, seven traded unchanged and one was untraded. All three Big Caps fell.

Opthea was the best, up 14 cents or 11.1 percent to $1.40, with 2.7 million shares traded. Antisense climbed seven percent; Impedimed, LBT and Proteomics improved more than four percent; with Alterity, Immutep and Resonance up more than two percent.

Polynovo led the falls, down 23 cents or 8.75 percent to $2.40, with 4.5 million shares traded. Actinogen and Orthocell lost eight percent or more; Pharmaxis was down 5.4 percent; Imugene, Nanosonics and Optiscan fell more than four percent; Clinuvel, Cochlear, Neuren, Oncosil, Prescient and Telix were down more than three percent; Amplia, Cyclopharm, Mesoblast, Next Science, Patrys, Resmed and Volpara shed two percent or more; Avita, CSL, Kazia, Paradigm, Pro Medicus and Universal Biosensors were down more than one percent; with Medical Developments down by less than one percent.

OPTHEA

Opthea says the US Food and Drug Administration has granted fast track designation for its OPT-302 for wet age-related macular degeneration (AMD).

Opthea said the FDA's fast track program helped "advance development and expedite the review of novel therapies for serious conditions for which there is an unmet medical need, with the aim of getting important new therapies to patients more quickly".

The company said the designation made it eligible for more frequent regulatory meetings and communications with the FDA, expediting the biologic drug application for its phase III trial, and for accelerated approval and priority review.

In March, Opthea said it would conduct two randomized, double-blinded, sham-controlled trials, with about 990 patients in each, evaluating OPT-302 in combination with ranibizumab (Lucentis) or OPT-302 with aflibercept (Eylea), compared to ranibizumab or aflibercept alone (BD: Mar 15, 2021).

Opthea managing-director Dr Megan Baldwin said that the "recognition from the FDA to grant OPT-302 fast track designation reflects the seriousness of wet AMD as a debilitating eye disease and the importance of advancing new therapies such as OPT-302 to address the significant unmet medical need for wet AMD patients, many of whom experience an incomplete response to [vascular endothelial growth factor-A] inhibitors despite regular, ongoing therapy."

Opthea was up 14 cents or 11.1 percent to $1.40 with 2.7 million shares traded.

CARTHERICS PTY LTD

Cartherics says it has ended its collaboration with the Hudson Institute and will work with the Australian Regenerative Medicine Institute.

Both the Hudson and the Australian Regenerative Medicine Institute (ARMI) are located at Melbourne's Monash University at Clayton,

Cartherics said that the collaboration included working with the Centre for Commercialization of Regenerative Medicine (CCRM), also at Monash Clayton.

Cartherics chief executive officer Prof Alan Trounson said the collaboration with ARMI was "an important step in our development and will embed industry and academic excellence in regenerative medicine and translation to clinical medicine in cancer".

The company said that academic appointments and access to related ARMI and Monash resources would be a benefit to Cartherics as it developed its off-the-shelf immune therapy products.

Cartherics said its allogeneic cell platform was based on induced pluripotent stem cells generated from donated cord blood that could be differentiated into natural killer (NK) cells, T-cells and other cells of the immune system.

The company said that Institute staff and students would benefit from closer association with the regenerative medicine company.

The Institute's external strategy and planning director and Centre for Commercialization of Regenerative Medicine chief executive officer Silvio Tiziani said that Cartherics would benefit as an industry member of CCRM Australia.

"As a partner organization to CCRM Australia, Cartherics will gain increased visibility to a global network of world-leading companies and access the business skills, leadership, potential funds for product development and receptor capacity for technologies and products available through the global CCRM network," Mr Tiziani said.

Cartherics said the collaboration coincided with the establishment of a facility for the company just north of Monash University.

Cartherics is a private company.

IMMUTEP

Immutep says the US Food and Drug Administration has approved its 154-patient, phase IIb trial of IMP321 in first-line head and neck squamous cell carcinoma.
Immutep said the FDA and institutional review board approved the randomized, controlled Tacti-003 trial, with US recruitment expected to begin by October 2021 and European and Australian sites to follow.
In March, the company said the trial would evaluate the safety and efficacy of its IMP321, or eftilagimod alpha, in combination with Merck Sharp & Dohme's Keytruda (pembrolizumab) and compared to pembrolizumab alone and would be conducted at more than 20 sites in the US, Australia and Europe (BD: Mar 16, 2021).
Today, Immutep said it was waiting for approval from Australian and European authorities and ethics committees for trial recruitment.
Immutep was up 1.5 cents or 2.8 percent to 54.5 cents with 5.6 million shares traded.

BIONOMICS

Bionomics says it has begun a phase IIb about 200-patient Attune trial to evaluate the tablet formulation of its BNC210 in patients with post-traumatic stress disorder (PTSD).
In 2018, Bionomics said its 193-patient, phase II trial of the anti-anxiety drug BNC210 in adults with PTSD failed to meet its primary endpoint (BD: Oct 2, 2018).
In 2019, the company said the BNC210 solid dose formulation achieved the blood levels necessary to meet efficacy endpoints (BD: Sep 26, 2019).
Today, Bionomics said the 900mg oral tablet formulation of BNC210 showed improved absorption compared to the previous liquid suspension formulation.
The company said the primary objective was to compare BNC210 to placebo for a decrease in PTSD symptoms after 12 weeks of treatment.
Bionomics said the Morrisville, North Carolina-based contract research organization, Premier Research would manage its 'Attune' study, with results expected by July 2023.
Bionomics fell half a cent or 2.5 percent to 19.5 cents.

CRESO PHARMA

Creso says Red Light Holland has ordered its first marijuana worth CHF152,220 (A$218,798) for Cannaqix cannabidiol lozenges and Cannaqix instant tea.
Last month, Creso said it would merge with the Ontario-based Red Light Holland to become the Highbrid Lab for recreational marijuana as well as "applied science, technology and innovation" (BD: Jun 17, 2021).
Today, the company said Red Light Holland's wholly-owned subsidiary SR Wholesale would market and distribute its marijuana-based products in the Netherlands.
Creso said the purchase order was "an important first step" in its potential merger with Red Light Holland to develop the Highbrid Lab.
Creso fell half a cent or 3.7 percent to 13 cents with 25.8 million shares traded.

TELIX PHARMACEUTICALS

The Hong Kong-based FIL says it has reduced its substantial shareholding in Telix from 24,978,764 shares (8.91%) to 22,280,031 shares (7.91%).
FIL said between January 4 and June 29, 2021 it bought 395,429 shares and sold 3,094,162 shares at prices ranging from $3.9034 to $6.1750 a share.
Telix fell 19 cents or 3.3 percent to $5.54 with 430,606 shares traded.

LUMOS DIAGNOSTICS HOLDINGS

Planet Innovation Holdings says it has become a substantial shareholder in Lumos with 40,124,915 shares or 26.7 percent of the company.

The Melbourne-based Planet Innovation said that in May 2019 it acquired 10,359,587 shares at 54 cents a share as part of internal restructuring agreements and a merger agreement.

The company said that on June 29, 2021 it converted 49,463,013 shares at 56 cents a share through investments and later sold 19,697,685 shares as part of the Lumos initial public offer.

Yesterday, Lumos opened on the ASX under the code of LDX following its $63 million initial public offer at $1.25 a share to develop and commercialize its point-of-care diagnostics (BD: Jul 5, 2021).

Lumos fell four cents or 3.05 percent to $1.27 with two million shares traded.

LUMOS DIAGNOSTICS HOLDINGS

RPS Diagnostics says it has become a substantial shareholder in Lumos with 15,647,189 shares or 10.4 percent of the company (see above).

The Sarasota, Florida-based RPS Diagnostics said in May 2019 it acquired 15,647,189 shares at 54 cents a share through a merger agreement.

LUMOS DIAGNOSTICS HOLDINGS

Perennial Value Management says it has become a substantial shareholder in Lumos with 11,733,971 shares or 7.81 percent of the company (see above).

The Sydney-based Perennial Value Management said between June 24 and 28, 2021 it bought 11,733,971 shares for $14,667,464 or an average price of $1.25 a share.

LUMOS DIAGNOSTICS HOLDINGS

Acorn Capital says it has become a substantial shareholder in Lumos with 8,973,877 shares or 5.98 percent of the company (see above).

The Melbourne-based Acorn Capital said on June 24 and 30, 2021 it bought 8,973,877 shares for $8,480,055 or an average price of 94.50 cents a share.

LITTLE GREEN PHARMA

Chief executive office Fleta Solomon says she has increased and been diluted in Little Green from 19,600,000 shares (11.1%) to 20,255,439 shares (8.7%).

Ms Solomon said that on March 12, 2021, she acquired 655,439 shares at no cost “on exercise of various rights” and was diluted in the recent placement.

Last month, Little Green said it had commitments to raise $27.2 million in a placement at 60 cents a share to buy a Denmark marijuana production facility (BD: Jun 22, 2021).

Little Green was up 1.5 cents or 1.7 percent to 90 cents.

LITTLE GREEN PHARMA

Bianca Hope Rinehart as trustee of the Hope Margaret Hancock Trust says she has become a substantial holder in Little Green with 26,739,029 shares or 11.50 percent.
Last week, Georgina Hope (Gina) Rinehart and Hancock Prospecting said they had become substantial shareholders in Little Green with 26,739,029 shares or 11.50 percent through a placement (see above).
Today, Ms Bianca Rinehart said she had become substantial in Little Green as a related party to the Gina Rinehart and Hancock investment.