Biotech Daily

Wednesday September 18, 2019

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: ANTISENSE UP 64%; PATRYS DOWN 9%**

*** CYNATA: 'FUJIFILM UP-TO $67m CYP-001 GVHD LICENCE'**

*** ANTISENSE UP 100% ON ATL1102 'POSITIVE DRUG EFFECT FOR DMD'**

*** EYE CO: HEMP SEED OIL FOR DRY AMD STEROIDS IN MICE**

*** ADALTA RECEIVES $3.5m R&D TAX INCENTIVE**

*** RECCE RECEIVES $164k R&D TAX INCENTIVE**

*** INVITROCUE EGM TO REMOVE DISSIDENT DIRECTORS**

*** COGSTATE 1m CEO BRAD O'CONNOR OPTIONS AGM**

*** ALTHEA PEAK PROCESSING EGM**

*** MGC PASSES 200 CANNEPIL, MXP100 PRESCRIPTIONS**

*** CRESO TAKES PHARMACIELO TRADING HALT TO SUSPENSION**

*** PETER, DIANA DIAMOND INCREASE, DILUTED TO 9% OF NOVITA**

*** NSW UNI BIO-ENGINEERING RESEARCH SHOWCASE NEXT TUESDAY**

MARKET REPORT

The Australian stock market was up 0.33 percent on Wednesday September 18, 2019, with the ASX200 up 21.8 points to 6,695.3 points. Twenty-three of the Biotech Daily Top 40 stocks were up, nine fell and eight traded unchanged.

Antisense was the best, up 100 percent to 9.4 cents before closing up three cents or 63.8 percent to 7.7 cents with 36.8 million shares traded. Cynata climbed 22.2 percent; Alterity was up 17.9 percent; Avita improved 13.5 percent; Opthea rose 8.4 percent; Kazia was up 7.45 percent; Genetic Signatures, Impedimed, Neuren, Pro Medicus and Proteomics were up five percent or more; Immutep improved 4.8 percent; Orthocell, Polynovo and Telix were up more than three percent; Amplia, Clinuvel and Volpara rose more than two percent; Nanosonics, Oncosil, Paradigm and Resmed were up more than one percent; with Cyclopharm and Medical Developments up by less than one percent.

Patrys led the falls, down 0.2 cents or 8.7 percent to 2.1 cents, with 2.9 million shares traded. LBT lost eight percent; Uscom fell four percent; Resonance was down 3.85 percent; Next Science, Starpharma and Universal Biosensors shed more than two percent; Mesoblast and Prescient were down more than one percent; with Cochlear and CSL down by less than one percent.

CYNATA THERAPEUTICS

Cynata says that Japan's Fujifilm will pay up to $US46 million ($A67 million) to licence its CYP-001 mesenchymal stem cell product for graft versus host disease.

In 2016, Cynata signed a $60 million agreement with Fujifilm for CYP-001 for graft versus host disease (GvHD) and its Cymerus stem cell technology (BD: Jan 22, 2017).

In 2017, the Tokyo-based Fujifilm Corp said it had become a substantial shareholder in Cynata with 8,088,403 shares or 10.01 percent, buying the shares at 49.1 cents a share (BD: Feb 20, 2017).

Today, Cynata said that Fujifilm had exercised its licence following the successful completion of the phase I trial of CYP001 for graft versus host disease in which “all safety and efficacy endpoints were achieved” (BD: Aug 30, 2018).

The company said it would receive $US3 million in cash as an upfront fee, along with milestone payments up-to $US43 million, including $US2 million on completion of the first phase II trial in the US, UK or Japan, $US3 million for completion of phase III trials $US12 million on submission of applications for regulatory approvals, $US16 million on acceptance of geographic marketing authorizations and first sales, $US10 million for extending the indication, as well as a 10 percent royalty on all future product sales if the product was commercialized in any country in which any licenced patents were granted or pending.

Cynata said it would pay $US10,000 to the Wisconsin Alumni Research Foundation for the patent rights, and would pay the Foundation “a mid-single digit percentage royalty on Fujifilm product sales and 30 percent of other amounts received from Fujifilm, including in respect of milestone payments”.

The company said that Fujifilm would bear responsibility for all costs of any further product development activities in relation to graft versus host disease, along with responsibility for regulatory submissions and commercialization.

Cynata said the non-dilutive upfront payment of $US3 million would lengthen its cash runway and support further investment in the upcoming phase II trials in critical limb ischemia and osteoarthritis, along with other potential future clinical programs.

The company said that the agreement included limited mechanisms for potential royalty adjustment on termination of the Wisconsin Alumni Research Foundation head licence, entry of a generic competitor or in-licencing third party enabling technology.

Cynata said it would enter into a separate agreement with Fujifilm for the supply of product by Cynata “for certain future product development activities at cost plus a moderate doubt digit manufacturing margin”.

The company said that Fujifilm’s “endorsement” of its Cymerus stem cell manufacturing platform “supported the continued commercialization of Cynata’s cell therapeutic products in other indications, including CYP002 for critical limb ischemia and CYP-004 for osteoarthritis”.

Cynata said that to facilitate ongoing partnering efforts “certain amendments have been made to the licence agreement” with the Foundation, particularly in relation to sub-licences and extending certain interim development milestones, while not changing the current milestone for obtaining approval from the US Food and Drug Agency (or an equivalent foreign agency) in 2026.

Cynata chief executive officer Dr Ross Macdonald said that “Fujifilm’s decision to exercise its licence option in GvHD is a clear validation of our Cymerus platform technology solution for manufacturing [mesenchymal stem cells] at scale”.

“We now look forward to Fujifilm taking this product through further clinical development activities and subsequently to market,” Dr Macdonald said.

Cynata climbed 31.5 cents or 22.2 percent to $1.735 with 1.6 million shares traded.

ANTISENSE THERAPEUTICS

Antisense jumped 100 percent on news that preliminary results from six patients dosed with ATL1102 for Duchenne muscular dystrophy indicate a “positive drug effect”.

In July, Antisense says five of the nine patients between 10 and 18 years of age had completed the 24-week dosing phase in its phase II trial of ATL1102 for Duchenne muscular dystrophy (DMD) at Melbourne’s Royal Children’s Hospital. (BD: Jul 24, 2019).

Today, the company said that six patients had completed dosing and preliminary data was “indicative of a positive drug effect of ATL1102 at the dose tested both at an immunomodulatory, that is effects on relevant immune cells, and disease progression, that is effects on muscle strength and function, levels.

Antisense said ATL1102 was an inhibitor of CD49d expression on certain immune cells such as T-cells and DMD patients with a greater number of T-cells with high levels of CD49d expression had more severe and rapid disease progression.

The company said the primary endpoints related to the safety and tolerability of ATL1102 and efficacy assessed in terms of its effects on disease processes and progression.

Antisense said no serious adverse events were reported.

The company said early indications of an immunomodulatory effect showed a downward trend during the treatment phase of certain immune cells, especially those expressing CD49d, and returned to starting levels post-dosing.

Antisense said the data showed improved strength compared to a six-month study that showed a significant mean reduction in upper body muscle strength and the data safety monitoring board recommended continuation of the trial.

Antisense chief executive officer Mark Diamond said that “given that there is currently no effective treatment for non-ambulant DMD patients, we are particularly encouraged by the preliminary data from the first six patients in this trial, which suggests a positive drug effect and may also demonstrate a meaningful slowing of disease progression compared to what might otherwise have been expected”.

“We expect this preliminary data to assist us in our planned regulatory interactions on the design and conduct of the phase IIb clinical trial that should allow examination of dosages of 25mg and higher to determine the optimal dosage,” Mr Diamond said.

Antisense said that ATL1102 was being developed as a novel treatment for the inflammation that exacerbates muscle fibre damage in Duchenne muscular dystrophy patients, currently treated with corticosteroids, which had a range of serious side effects when used for a prolonged period as required in Duchenne muscular dystrophy.

The company said it was the first occasion ATL1102 has been dosed for an extended duration, six months, in this patient population of non-ambulant Duchenne muscular dystrophy patients, so it expected the safety observations would be important support for the proposed longer dosing in a phase IIb trial.

Antisense said the progress of the final three patients, due to complete dosing in November, “appears consistent with this view that the drug is showing activity”.

The company said that a 2016 publication evaluated disease progression in non-ambulant boys over a six-month period, where a significant mean reduction in upper body muscle strength of the subjects was observed.

Antisense said that “by comparison, the data on the first six patients completing dosing in the ATL1102 trial, shows a distinct improvement in these strength parameters over the losses noted in the … publication”.

The company said it was further analyzing the preliminary trial data to confirm the level and rate of response to therapy within the trial to date.

Antisense climbed as much as 100 percent to 9.4 cents before closing up three cents or 63.8 percent to 7.7 cents with 36.8 million shares traded.

EYE CO

Eye Co says it will study the delivery of ophthalmic steroids using hemp seed oil in a mouse model of dry age-related macular degeneration.
Eye Co said the second series of studies using the Australian National University mouse model would examine safety, efficacy, enhanced bioavailability and dosage accuracy when ophthalmic steroids such as triamcinolone acetonide and fludrocortisone acetate were delivered intra-vitreally in hemp seed oil as a carrier.
The company said that ophthalmic steroids such as triamcinolone acetonide and fludrocortisone acetate were highly water insoluble and only available in an aqueous suspension, had proved “notoriously difficult to deliver intravitreally”.
Eye Co said the ANU mouse model involved the development of lesions that mimicked dry age-related macular degeneration (d-AMD) resulting from exposure to bright light.
The company said it had filed patents relating to the composition and treatment of age-related macular degeneration with hemp seed oil or a pharmaceutical active extract.
Eye Co said the patent application was directed to the use of compositions comprising oils such as hemp seed oil as a carrier of pharmaceutical actives for intravitreal administration.
Eye Co is a private company.

ADALTA

Adalta says it has received $3,498,774 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Adalta said that the rebated related to research and development expenditure for the year to June 30, 2019.
Adalta was up two cents or 14.3 percent to 16 cents.

RECCE PHARMACEUTICALS

Recce says it has received $163,672 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Recce said that the rebate related to research and development expenditure for the year to June 30, 2019.
Recce was up 2.5 cents or 10.9 percent to 25.5 cents.

INVITROCUE

Invitrocue says an extraordinary general meeting has been called to remove directors Prof Hanry Yu and Kit Wei Lui.
Earlier this month, Invitrocue filed two board spill motions, one from Prof Yu, Mr Lui and Ms Ng to remove chief executive officer Dr Steven (Boon Sing) Fang as a director and one from Dr Fang and directors Gary Pace and Andreas Lindner to remove Prof Yu and Mr Lui as directors (BD: Sep 9, 2019).
Last week, the company said Prof Yu, Mr Lui and Ms Ng called a meeting to remove recently appointed director Geoffrey Thomas (BD: Sep 10, Sep 11, 2019).
The company later said the meeting to remove Dr Fang would be held at Macpherson Kelley, Level 21, 20 Bond Street, Sydney on October 11, 2019 at 11am (AEDT) but a time and place had not been set for the meeting proposing to remove Mr Thomas.
The meeting to remove Prof Yu and Mr Lui will be held at Room 25A, Level 25, 108 St Georges Terrace, Perth, Western Australia on October 18, 2019 at 2pm (AWST).
Invitrocue was in a suspension and last traded at six cents.

COGSTATE

Cogstate says its annual general meeting will vote to issue Mr O'Connor 1,000,000 options exercisable at the share price on October 21, 2019 plus four cents.
Cogstate said the options would issued in two tranches of 500,000 options each pending $US30 million in clinical trials sales contracts in the year to June 30, 2021 and a positive earnings before interest, taxation, depreciation and amortization (Ebitda) for the year to June 30, 2021, respectively.
The company said that the meeting vote placement shares to Australian Ethical Investment and Eisai Co, elect directors Ingrid Player and Dr Richard Mohs and adopt the renumeration report.
The meeting will be held at the Business Centre, Level 6, Tower Two, Collins Square, 727 Collins Street, Melbourne on October 21, 2019 at 11am (AEDT).
Cogstate was unchanged at 26.5 cents.

ALTHEA GROUP HOLDINGS

Althea says a meeting has been called to approve the acquisition of Canada marijuana extraction and contract manufacturing business Peak Processing Solutions.
Althea said it would vote to acquire 100 percent of shares in 2613035 Ontario Limited or Peak Processing Holdco, from 2707813 Ontario Inc, a company controlled by former director Gregg Battersby.
The company said it would acquire 46 percent of shares in 2682130 Ontario Limited or Peak Processing Operationsco, from nine employees and independent contractors, with 54 percent retained by Peak Processing Holdco.
Althea said it would vote to issue up to 15,707,518 shares to 2707813 Ontario Inc, controlled by Mr Battersby.
The company said it would vote to issue up to, in aggregate, 10,146,126 shares to employee shareholders of Peak Processing Operationsco.
Althea said it would vote to issue 180,000 shares to Panrich as trustee for the Newbold Family Super Fund, controlled by chairman Andrew Newbold.
Althea said it would vote to issue 30,000 shares to Taylor Dobson Perpetual, jointly controlled by Penelope Dobson and her husband.
The meeting will be held at DLA Piper Australia, Level 21, 140 William Street, Melbourne on October 14, 2019 at 10am (AEDT).
Althea fell three cents or 3.8 percent to 76 cents.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says it has passed 200 prescriptions for its 5.0 percent tetrahydrocannabinol Cannepil and 100 percent cannabidiol MXP100 products in Australia and the UK.
MGC said this was an increase on the 100 registered or prescribed patients in mid-August 2019.
The company said it added 52 new patients in the first two weeks of September and the average number of new patients was increasing on a weekly basis.
MGC said its Cannepil and MXP100 products were prescribed in Australia under the special access scheme and in the UK under the early access to medicines scheme through specialized doctors permitted to prescribe phyto-cannabinoid derived medicines.
MGC was unchanged at four cents with 10.5 million shares traded.

CRESO PHARMA

Creso has requested a voluntary suspension to follow the trading halt requested “pending an announcement regarding the proposed acquisition of the company by Pharmacielo” (BD: Sep 16, 2019).
Creso last traded at 38.25 cents.

NOVITA HEALTHCARE

Peter and Diana Diamond say they have increased and been diluted in Novita from 55,000,000 shares (12.24%) to 60,000,000 shares (9.45%).
The Peppermint Grove, Western Australia-based Mr and Ms Diamond said that they acquired 5,000,000 shares for $50,000 or one cent a share and were diluted in the $1,855,796 entitlement offer and shortfall shares on August 28, 2019.
Novita fell 0.1 cents or 7.7 percent to 1.2 cents with 14.1 million shares traded.

UNIVERSITY OF NEW SOUTH WALES

The University of New South Wales says it will hold an afternoon bioengineering research ‘showcase’ next Tuesday, September 24, 2019.
The University said that the event would celebrate “the latest developments in connected healthcare, bionics, bioengineered materials and technologies, biomolecular innovations and medical imaging analytics”.
The University said that the showcase, titled ‘Bioengineering for a Healthy Future’, would begin with a panel discussion moderated by University provost Prof Anne Simmons, with Ausbiotech chief executive officer Lorraine Chiroiu, Johnson & Johnson senior director global innovation Kathy Connell, Brandon Capital managing-director Dr Stephen Thompson, Prince of Wales Hospital cardiac specialist Dr Sze-Yuan Ooi and the Graduate School of Biomedical Engineering’s Prof Nigel Lovell.
The University of New South Wales said there would be a poster session highlighting emerging technologies from the Faculty of Medicine and Graduate School of Biomedical Engineering, among others.
The University said the free event was “an opportunity to discover the University of New South Wales’ latest research capabilities and is designed to connect you with leading researchers as well as network with other guests from industry and government”.
The showcase will be held in Leighton Hall, John Niland Scientia Building, University of New South Wales, Kensington, Sydney on September 24, 2019 from 4pm until 7pm with drinks and canapes.
To register, go to http://unsw.to/healthyfutureshowcase.