Biotech Daily

Wednesday June 10, 2020

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PROTEOMICS UP 23%; AMPLIA DOWN 11%**

*** OPTHEA CLAIMS OPT-302 DME 'NON-SIGNIFICANT' SUCCESS**

*** BIO-MELBOURNE: DR ANDREA DOUGLAS WINS LEADERSHIP AWARD**

*** ADALTA READY FOR AD-214 FOR LUNG DISEASE TRIAL**

*** TELIX: NEW TLX591-CDX DATA FOR US NDA**

*** IMMURON PLEADS SCHULTZ TO ASX 442% PRICE QUERY**

*** MACH7 CAPITAL RAISE TO BUY CLIENT OUTLOOK FOR $41m**

*** MICRO-X SUBMITS 510(k) TO FDA FOR ROVER MOBILE X-RAY**

*** MEDIBIO PLACEMENT RAISES $500k, RIGHTS FOR $1.5m MORE**

*** RHINOMED: UNNAMED US DRUG STORE ORDERS PRONTO CLEAR**

*** PAINCHEK APPLIES FOR CANADA PAIN ASSESSMENT CLEARANCE**

*** AVITA SCHEME MEETING TO MOVE TO THE US**

*** OSPREY OPTION EXERCISE DATES**

*** CRESO COMPLETES DUE DILIGENCE TO SELL MARIJUANA IN CANADA**

*** ADHERIUM: TRUDELL 15%, ONE FUNDS 8%, PHILLIP THEMATIC 5.5%**

*** ORTHOCELL APPOINTS DR LESLIE WISE EXECUTIVE DIRECTOR**

MARKET REPORT

The Australian stock market was up 2.44 percent on Wednesday June 10, 2020, with the ASX200 up 146.2 points to 6,144.9 points. Fourteen of the Biotech Daily Top 40 stocks were up, 21 fell and five traded unchanged. All three Big Caps were up.

Proteomics was the best, up 10.5 cents or 22.8 percent to 56.5 cents, with 869,283 shares traded. Actinogen was up 12 percent; Patrys climbed 7.1 percent; Optiscan improved 4.55 percent; Mesoblast was up 3.7 percent; CSL, Dimerix and Pro Medicus rose more than two percent; Cynata, Kazia and Orthocell were up more than one percent; with Cochlear, Genetic Signatures, Medical Developments, Nanosonics, Paradigm and Resmed up by less than one percent.

Amplia led the falls, down 1.5 cents or 11.1 percent to 12 cents, with 356,728 shares traded. LBT and Opthea lost more than nine percent; Osprey fell 7.1 percent; Cyclopharm and Impedimed shed more than six percent; Immutep and Neuren were down more than five percent; Uscom fell 4.4 percent; Oncosil lost 3.85 percent; Next Science, Pharmaxis, Polynovo, Resonance, Telix, Universal Biosensors and Volpara shed more than two percent; with Avita, Clinuvel, Prescient and Starpharma down by less than one percent.

OPTHEA

Opthea says its 144-patient, phase IIa trial of OPT-302 with aflibercept, or Eylea, for diabetic macular oedema met its primary endpoint, but without statistical significance.

Opthea said in a media release to the ASX that “52 percent of patients in the OPT-302 combination and 60 percent of patients in the Eylea control group gained more than or equal to five letters”, with a mean increase of 5.9 letters and 6.1 letters, respectively.

The company said that “the trial was not powered to detect differences between the treatment groups”.

Opthea said the trial was designed with a pre-specified primary efficacy endpoint of five letters or more vision gain, with a treatment response rate of 38 percent or more, based on previously published studies.

The company said that 2.0mg OPT-302 was safe and well-tolerated.

In January, Opthea said the primary efficacy endpoint was the clinical response rate, defined as the proportion of patients receiving combination OPT-302 and aflibercept achieving a five-letter or more gain in visual acuity at week-12 compared to baseline.

Opthea said at that time that secondary efficacy measures include mean visual acuity, macular thickness, improvement in diabetic retinopathy severity score and durability of response.

Today, Opthea chief executive officer Dr Megan Baldwin told Biotech Daily that the trial was never powered to show statistical significance on the primary endpoint.

Dr Baldwin said that of the 115 evaluable patients, 52 percent of 75 patients (39 patients) in the combination OPT-302 with aflibercept arm and 60 percent of the 40 patients (24 patients) in the aflibercept alone arm achieved five or more letters above baseline at 12 weeks.

“It’s not a binary outcome like the phase IIb [wet age-related macular oedema] trial,” Dr Baldwin said.

“We would need to have 300 to 400 patients,” Dr Baldwin said.

“It’s shown signals to move forward,” Dr Baldwin said.

In the media release, Opthea said that 26.7 percent of OPT-302 combination patients gained 10 or more letters from baseline to week 12, compared to 22.5 percent in the Eylea control group.

The company said that 12 percent of patients in the OPT-302 combination group gained 15 letters or more, compared to 7.5 percent in the Eylea control group.

Opthea said that 2.7 percent of the OPT-302 combination therapy group lost five letters or more, compared to five percent in the Eylea control group.

Biotech Daily asked Dr Baldwin for the numbers underlying the percentage improvements, but that had not been received at the time of publication.

Last year, Opthea jumped 160.1 percent to $2.25 on news that its 366-patient, phase IIb trial of OPT-302 for wet age-related macular degeneration met its primary endpoints with statistical significance ($p = 0.0107$) (BD: Aug 7, 2019).

Opthea said at that time that the higher dose 2.0mg OPT-302 vascular endothelial growth factor receptor 3 (VEGF-3) with ranibizumab (Lucentis, a VEGF-A inhibitor compound) showed the statistically significant difference at 24 weeks of treatment, compared to both low dose 0.5mg OPT-302 with ranibizumab and control with ranibizumab.

Today, Dr Baldwin told Biotech Daily the company’s priority was wet age-related macular oedema and it would need to run two phase III trials, each costing about $80 million.

Dr Baldwin said that Opthea was “looking at multiple ways of funding the trials” and would consider diabetic macular oedema “once we’ve worked out the strategy”.

Opthea initially rose as high as $3.60 on the news, but closed down 31 cents or 9.2 percent at $3.05 with four million shares traded.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says CSL's head of organization transformation Dr Andrea Douglas has won the 2020 Women in Leadership Award.
The network said that the winners were announced at a virtual ceremony opened by Victoria Governor Linda Dessau attended by more than 160 guests.
The Bio-Melbourne Network said that Victoria's Parliamentary Secretary for Jobs Jane Garrett presented the awards with the 2020 Most Valuable Women in Leadership Award going to Andhealth founder Bronwyn Le Grice and the Emerging Women in Leadership Award won by Leica Biosystems Asia-Pacific marketing director Dr Ewa Douroux.
Bio-Melbourne Network chair Lusia Guthrie said that the industry organization was "impressed with the number of nominations for these awards and are in awe of the phenomenal achievements of women across our sector".

ADALTA

Adalta says it has ethics approval to begin a 94-patient, phase I trial of AD-214 for interstitial lung disease, including patients with idiopathic lung disease.
Adalta said the trial would investigate safety and tolerability as the primary endpoint and pharmaco-kinetics and pharmaco-dynamics as secondary endpoints.
According to www.clinicaltrials.gov, the trial will be the first-in-human, multi-centre, randomized, double-blind, placebo-controlled and dose escalating trial of AD-214.
The company said it expected to begin screening in healthy volunteers for part A of the trial later this month and to administer AD-214 to the first patient in the second half of July.
Adalta said it would begin parts B and C of the trial, subject to satisfactory completion of part A, in early 2021 and expected safety results in the beginning of 2021.
The company said that development of a radio-labelled version of AD-214 for positron emission tomography imaging had recommenced and was on-track for use in parts B and C in 2002, adding "significant clinical and partnering value to the phase I program".
Adalta chief scientific officer Prof Michael Foley said the approval was "a milestone that Adalta has been working towards for many years".
Adalta was up 1.4 cents or 17.3 percent to 9.5 cents with 1.5 million shares traded.

TELIX PHARMACEUTICALS

Telix says it has new data supporting its TLX591-CDx for prostate cancer imaging, which will be included in its US Food and Drug Administration new drug application.
Telix said the new data showed that TLX591-CDx, or 68-gallium-prostate-specific membrane antigen-11 (68-Ga-PSMA-11), was superior to conventional imaging in men with newly diagnosed high-risk prostate cancer, and it expected the new data inclusion to be completed in six to eight weeks.
Telix chief executive officer Dr Colin Hayward said that "gallium PSMA imaging is an important advancement in prostate cancer imaging, including the setting of high-risk men prior to curative intervention".
"New data supports the superior accuracy of 68-Ga-PSMA-11 imaging over conventional imaging in this patient setting and also clearly demonstrates that 68-Ga-PSMA-11 imaging led to improved clinical and treatment decision making," Dr Hayward said.
"The opportunity to potentially include additional analysis in our [new drug application] is worthwhile and may ultimately enable us to offer our product to a significantly larger number of patients in need," Dr Hayward said.
Telix fell three cents or 2.1 percent to $1.385 with 1.6 million shares traded.

IMMURON

Immuron has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price rose 442.2 percent from 8.3 cents yesterday June 9 to a high of 45 cents today June 10, 2020 and noted "the very significant increase" in the trading volume.
Yesterday, Immuron said its research collaboration on campylobacter and Escherichia coli with the US Naval Medical Research Center (NMRC) was back on-track and the NMRC had requested a pre-investigational new drug application meeting with the US Food and Drug Administration (BD: Jun 9, 2020).
On the Nasdaq overnight, Immuron was up $US17.90 or 852.3 percent to $US20 ($A28.61) with 75.7 million shares traded.
Immuron was in a trading pause and last traded up 21.7 cents or 261.45 percent to 30 cents with 41.2 million shares traded.

MACH7 TECHNOLOGIES

Mach7 says it hopes to raise $34.8 million through a placement and rights offer to buy the Waterloo, Ontario-based Client Outlook for $CA38.5 million ($A40.8 million) in cash.
Mach7 said it hoped to raise $3.7 million through an institutional placement and $31.1 million through a one-for-four, non-renounceable, entitlement offer at 68 cents a share, fully underwritten by Morgans Corporate.
The company said the offer price was at a 13.9 percent discount to the last traded price of 79 cents on June 9, 2020.
Mach7 said the record date for the retail entitlement offer was June 12, would open on June 17 and close on June 26, 2020.
The company said eligible shareholders would be able to apply for additional shares of up to 50 percent of their entitlement in a top up facility through the entitlement offer.
Mach7 said the funds would be used to acquire Client Outlook, which was a single enterprise viewing and integration platform, had more than 90 customers in North America and Asia and had $8.8 million in revenue for the year to January 31, 2020.
The company said the acquisition would expand the addressable market from $US750 million ($A1,076.2 million) to $US2,750 million, would expand its customer install base and provide an additional $40 million in revenue opportunities in the near term.
Mach7 said it would retain two founder executives, a head of sales and a head of engineering to provide continuity and it expected to hire an integration manager to manage the integration, expected to be completed by the end of 2020.
The company said it expected to complete the acquisition by July 10, 2020.
Mach7 was in a trading halt and last traded at 79 cents.

MICRO-X

Micro-X says it has submitted a 510(k) application to the US Food and Drug Administration for its Rover mobile X-ray for deployed military medical facilities.
Micro-X said it had received an acknowledgement letter from the FDA's Centre for Devices and Radiological Health and a 90-day review would begin.
The company said it planned to seek Conformité Européenne (CE) mark and Australian Therapeutic Goods Administration registration within the next 12 months.
Micro-X fell half a cent or 3.6 percent to 13.5 cents with 1.7 million shares traded.

MEDIBIO

Medibio says it has commitments to raise $500,000 through a placement at 0.6 cents a share and hopes to raise a further $1,517,195 million through a one-for-four underwritten, non-renounceable entitlement offer.
Medibio said the issue price was at a 15 percent discount to the 15-day volume weighted average price of 0.7 cents at June 4, 2020.
The company said the entitlement offer had a record date of June 15, would open on June 18 and close on June 29, 2020.
Medibio said the funds would be used to undertake the depressive burden trial, to commercialize its Mebsleep and Ilumen products, to develop a consumer application and for general working capital.
The company said CPS Capital Group was the lead manager, broker and corporate advisor to the placement and underwriter to the entitlement offer and would be paid a six percent capital raising fee and a $20,000 underwriting fee.
Medibio said CPS would subscribe for 20,000,000 unlisted options at an issue price of 0.001 cents an option and exercisable at 3.0 cents by June 2, 2022.
Medibio was up 0.1 cents or 16.7 percent to 0.7 cents with 13.6 million shares traded.

RHINOMED

Rhinomed says it has purchase orders from an unnamed US drug store chain for its Pronto Clear nasal decongestion technology.
Rhinomed said the drug store chain would stock Pronto Clear in the cough, cold and influenza category in 6,336 shops across the US.
The company said pricing details were confidential and the identity of the drug store chain would be announced when stock appeared on shelves in August or September 2020.
Rhinomed chief executive officer Michael Johnson said, “this is a significant expansion in our global distribution network”.
“To put that in context, there are now more new stores stocking Rhinomed’s products than there are pharmacies in Australia,” Mr Johnson said.
Rhinomed fell 0.1 cents or 1.2 percent to 8.4 cents.

PAINCHEK

Painchek says it has made a class one medical device clearance submission to Canada Health for its Painchek mobile application pain assessment software.
Painchek said Canada Health had a 120-day review timeframe, which would allow the company to sell its products and services in Canada this year.
Painchek was up one cent or 6.9 percent to 15.5 cents with 2.05 million shares traded.

AVITA MEDICAL

Avita says it will hold a scheme meeting to approve the proposed relocation of the company to the US (BD: Apr 21, 2020).
The meeting will be held virtually on Monday, June 15, 2020 at 9am (AEST), Sunday June 14, 2020 at 7pm (US EDT).
Avita fell half a cent or one percent to 48 cents with 18.1 million shares traded.

OSPREY MEDICAL

Osprey says the first exercise date for options under the three-for-one partially underwritten renounceable entitlement offer will be June 15, 2020.
In April, Osprey said it had raised $10,244,920 through the entitlement offer and reserved the right to place the remaining $5,299,785 shortfall (BD: Apr 29, 2020).
Yesterday, the company said it placed $2.6 million of the shortfall (BD: June 9, 2020).
Today, Osprey said 853,743,330 options were issued under the offer with the first window to exercise them at 1.4 cents each on June 15, with the balance exercisable on October 14, 2020 and February 15, 2021.
Osprey fell 0.1 cents or 7.1 percent to 1.3 cents with 6.3 million shares traded.

CRESO PHARMA

Creso says wholly owned subsidiary Mernova Medicinal Inc has completed legal due diligence and will begin selling its dried and fresh marijuana in Canada.
In May, Creso said it had received a sales licence from Health Canada "pending additional information" (BD: May 11, 2020).
Creso was up 0.2 cents or 3.9 percent to 5.3 cents with 6.7 million shares traded.

ADHERIUM

The London, Ontario-based Trudell Medical says its 89,364,179 shares substantial holding in Adherium has been diluted from 17.98 percent to 14.86 percent.
In May, Bioscience Managers raised $5 million for Adherium (BD: May 26, 2020).
The Sydney-based One Funds Management says its 48,808,957 shares substantial holding in Adherium has been diluted from 9.82 percent to 8.12 percent.
The Singapore-based Phillip Thematic Fund says its 33,333,333 shares substantial holding in Adherium has been diluted from 6.71 percent to 5.54 percent.
Adherium was unchanged at 2.7 cents.

ORTHOCELL

Orthocell says it has appointed Dr Leslie Wise as an executive director.
Orthocell said Ms Wise had more than 20 years' experience in US reimbursement, life sciences and medical technology, including at Bristol Myers-Squib, Sanofi and Biomet Orthopaedics.
The company said Dr Wise was currently the principal of Evidence Matters and was previously Angio Dynamics head of healthcare economics and healthcare policy, and a director of Sanarus.
Orthocell chief executive officer Paul Anderson told Biotech Daily that Dr Wise held a Bachelor of Arts and Doctor of Jurisprudence from the Ann Arbor-based University of Michigan and a Master of Science from England's University of Sheffield.
Orthocell said that in addition to director fees, it would issue Dr Wise 2,000,000 options, vesting over two years and exercisable at a 15 percent premium to the seven-day volume weighted average price, expiring five years from the issue date.
Orthocell was up half a cent or 1.4 percent to 36 cents.