Biotech Daily

Tuesday October 27, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: IMPEDIMED UP 5%; AMPLIA DOWN 11.5%**

*** TGA APPROVES CLINUVEL'S SCENESSE FOR EPP**

*** TGA APPROVES ATOMO, ACCESS BIO SARS-COV-2 RAPID ANTIGEN TEST**

*** DIMERIX: 'DMX-200 REDUCES KIDNEY DISEASE PROTEINURIA'**

*** ALTERITY STARTS MSA NATURAL HISTORY STUDY**

*** TELIX COMPLETES PHASE I RENAL CANCER STUDY ENROLMENT**

*** ADALTA: AD-214 SAFE IN 21 PHASE I VOLUNTEERS**

*** ZELIRA LAUNCHES HOPE MARIJUANA FOR AUTISM IN AUSTRALIA**

*** RHYTHM ADDS 7th COLOSTAT TRIAL SITE**

*** OPTHEA RECEIVES $8.5m R&D TAX INCENTIVE**

*** ACTINOGEN RECEIVES $2.9m R&D TAX INCENTIVE**

*** ACRUX RECEIVES $521k R&D TAX INCENTIVE**

*** COGSTATE: 19% OPPOSE REMUNERATION REPORT**

*** BARD1 30-TO-1 CONSOLIDATION AGM**

*** SUDA 3m DIRECTOR DR MICHAEL BAKER OPTIONS AGM**

*** OPTISCAN 35.7m DIRECTOR, INVESTOR OPTIONS AGM**

*** EMVISION 1.5m DIRECTOR OPTIONS AGM**

*** NUHEARA 6m DIRECTORS OPTIONS AGM**

*** KARST PEAK, ADAM LEITZES TAKE $21m GENETIC SIGNATURES PROFIT**

MARKET REPORT

The Australian stock market fell 1.7 percent on Tuesday October 27, 2020, with the ASX200 down 104.6 points to 6,051.0 points.

Five of the Biotech Daily Top 40 stocks were up, 28 fell and seven traded unchanged. All three Big Caps fell.

Impedimed was the best of the five, on its Appendix 4C quarterly report citing increased annual recurring revenue, despite a small fall in customer receipts, up 0.4 cents or 4.8 percent to 8.7 cents, with 2.2 million shares traded. Dimerix improved 3.7 percent; Uscom rose 2.9 percent; with Paradigm and Proteomics up more than one percent.

Amplia led the falls, down three cents or 11.5 percent to 23 cents, with 719,162 shares traded.

Compumedics lost 9.1 percent; Prescient retreated 6.7 percent; Alterity shed 5.4 percent; Antisense, Avita, Osprey and Volpara fell four percent or more; Imugene, Mesoblast, Telix and Universal Biosensors were down three percent or more; Medical Developments, Neuren, Opthea, Optiscan, Orthocell and Pro Medicus shed two percent or more; Clinuvel, Cochlear, CSL, Cyclopharm, Cynata, Genetic Signatures, Immutep, Nanosonics, Next Science and Resmed were down more than one percent; with Kazia, Polynovo and Starpharma down by less than one percent.

CLINUVEL PHARMACEUTICALS

Clinuvel says the Australian Therapeutic Goods Administration has approved Scenesse for erythropoietic protoporphyria (EPP).

In 2016, Clinuvel said European marketing authorization for Scenesse was “under a strict risk management plan” and last year, said the US Food and Drug Administration had approved Scenesse for EPP (BD: May 18, 2016; Oct 9, 2019).

Today, the company said Scenesse, or 16mg afamelanotide, was the first treatment that protected EPP patients from wavelengths of light that caused phototoxicity by reducing the number and severity of reactions and increasing the amount of time patients could be exposed to light.

Clinuvel said Scenesse would be available to Australian patients as a prescription medication by trained and accredited healthcare professionals, who would be trained under an accreditation program by the company.

Clinuvel chief scientific officer Dr Dennis Wright said that it was “deeply satisfying to share with all involved that Scenesse, an innovative, Australian-developed drug, has been approved to treat Australian EPP patients”.

“Our team is particularly grateful to individuals and families within the Australian EPP patient community who have supported our development program over the past 15 years as we work towards enabling treatment access,” Dr Wright said.

“The TGA is the third global regulatory agency to evaluate and approve Scenesse for EPP,” Dr Wright said.

“Our step-wise approach to regulatory engagement continues to be validated by today’s news while we progress discussions in other regions where EPP patients lack access to treatment,” Dr Wright said.

Clinuvel fell 34 cents or 1.55 percent to $21.61 with 137,054 shares traded.

ATOMO DIAGNOSTICS

Atomo says the Australian Therapeutic Goods Administration has approved Access Bio's severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) rapid antigen test.
In September, Atomo said that, pending approvals, it would sell Access Bio's Sars-Cov-2 test in Australia, New Zealand and India (BD: Sep 29, 2020).
Today, the company said the rapid antigen blood test was a nasopharyngeal swab test that screened for antigens produced in response to Sars-Cov-2, the virus that caused Covid-19.
Atomo said results from the test were available after 10 minutes and could benefit early identification compared to polymerase chain reaction tests.
The company said it had engaged Health Solutions Group Australia to provide professional testing services to customers through pop-up style clinics and it would now be able to supply the test to departments of health, laboratories, medical practitioners and healthcare professionals in Australian aged care facilities.
Atomo said that the Sars-Cov-2 antigen test would be sold alongside its own Covid-19 antibody test and its HIV self-test.
Atomo was up four cents or 12.9 percent to 35 cents with 9.5 million shares traded.

DIMERIX

Dimerix says its DMX-200 has reduced proteinuria in both its phase IIa trial for focal segmental glomerulosclerosis and its phase II trial for diabetic kidney disease.
In July, Dimerix said its 10-patient, phase IIa trial of DMX-200 for focal segmental glomerulo-sclerosis (FSGS) met its primary and secondary endpoints, reducing proteinuria by an average 29 percent in seven patients, compared to placebo (BD: Jul 29, 2020).
Last month, the company said its 45-patient, phase II trial of DMX-200 for diabetic kidney disease did not meet its primary endpoint of change in 24-hour albuminuria compared to a placebo (BD: Sep 14, 2020).
Today, Dimerix said DMX-200 was safe and well-tolerated in both studies and its advisory board unanimously agreed to progress DMX-200 to a larger, pivotal FSGS study.
The company said the studies observed a high correlation between severity of patient proteinuria and the molecular target of DMX-200, which also reduced the inflammatory biomarker monocyte chemo-attractant protein-1 by 39 percent compared to a placebo.
The company said further analysis of the data was underway.
Dimerix said the data supported the proposed mechanism of action of DMX-200 being effective in diseases with active inflammatory processes driving disease progression.
The company said that "an order of treatment effect was noted" in both focal segmental glomerulo-sclerosis and diabetic kidney disease studies, with the treatment group receiving DMX-200 first not returning to baseline during the wash-out period, resulting in a significantly lower starting baseline proteinuria in the second period.
Dimerix said that "a potential disease modifying effect has not been ruled out, where the patient may have continued DMX-200 benefit through the washout period, after they had stopped taking DMX-200 [and] this can be an indicator that the drug may be having a lasting positive effect on the function of the kidney".
Dimerix managing-director Dr Nina Webster said that the positive correlation of reduced inflammatory biomarkers with a reduction in proteinuria following treatment with DMX-200 "further strengthens our understanding of how DMX-200 is delivering clinically meaningful outcomes for these kidney patients".
Dimerix was up one cent or 3.7 percent to 28 cents with 3.1 million shares traded.

ALTERITY THERAPEUTICS

Alterity says it has enrolled an initial cohort of 10 early-stage patients in its up-to one-year natural history study of multiple system atrophy, with enrolment continuing as required.
In May, Alterity said a phase I trial of ATH434 for multiple system atrophy (MSA), a form of atypical Parkinsonism with no approved therapy, showed that it crossed the blood brain barrier in humans at levels indicating efficacy (BD: May 21, 2020).
In June, the company said the US Food and Drug Administration had agreed to the proposed patient population, safety monitoring plan and strategy for evaluating drug exposure in its phase II trial, but non-clinical investigations would be required and with the FDA it would develop an endpoint best suited for patients (BD: Jun 30, 2020).
Today, Alterity said the natural history study, in collaboration with Vanderbilt University Medical Center, aimed to track the progress of early-stage MSA patients to inform its phase II study design and the selection of biomarkers.
The company said that natural history studies were “important for characterizing disease progression in selected patient populations”.
Alterity said that patients would undergo detailed neurological examination, clinical rating scales of motor, autonomic and activities of daily living symptoms and specialized neuroimaging and assessment of protein biomarkers in diverse biological specimens.
Alterity fell 0.2 cents or 5.4 percent to 3.5 cents with 19.4 million shares traded.

TELIX PHARMACEUTICALS

Telix says it has completed the enrolment of six patients in phase I of its 40-patient phase I/II study of TLX250-CDx for renal cancer in Japan.
Telix said the multi-centre zirconium dosing and comparison in Japan (Zirdac-JP) study aimed to evaluate the safety, tolerability, radiation dosimetry and pharmacokinetics and pharmacodynamics of TLX250-CDx (BD: Aug 18, 2020).
The company said the patient population was selected to be identical to its global phase III Zircon trial of TLX250-CDx for kidney cancer, which was expected to complete recruitment by April 2021.
Telix said that it expected to begin the phase II component of the study in early 2021, following data review and consultation with the Japanese Pharmaceuticals and Medical Devices Agency.
Telix fell five cents or 2.95 percent to $1.645.

ADALTA

Adalta says it has treated 21 healthy volunteers and recorded no safety concerns so far in its phase I trial of AD-214.
In June, Adalta said it would begin a multi-centre, randomized, double-blind, placebo-controlled and dose escalating, 94-patient, phase I trial of AD-214 in healthy volunteers to investigate the safety, tolerability, pharmaco-kinetics and pharmaco-dynamics for interstitial lung disease, including idiopathic lung disease (BD: Jun10, Jul 23, 2020).
Today, the company said the data, which would be presented by managing director Dr Tim Oldham at the Ausbiotech Invest and Partnering Conference on October 29, 2020, found that the two patients who received the highest five milligrams per kilogram (mg/kg) dose passed the dose limiting adverse event observation period.
The company said it administered between 0.1mg/kg and 5mg/kg of AD-214 or placebo to 21 healthy participants and planned a total maximum dose of 20mg/kg for the trial.
Adalta fell one cent or eight percent to 11.5 cents with two million shares traded.

ZELIRA THERAPEUTICS (FORMERLY ZELDA THERAPEUTICS)

Zelira says it has launched its marijuana Hope products for autism in Australia through the Australian Therapeutic Goods Administration's special access scheme.
Last year, the then Zelda said it would merge with Ilera Therapeutics to form Zelira and gain access to the Hope portfolio (BD: Oct 9, Nov 20, 2019).
In November 2019, the company said the UK-based Health House Holdings would distribute its Hope marijuana products for autism spectrum disorder in Australia and the UK (BD: Nov 21, 2019).
Today, Zelira managing director Dr Richard Hopkins said that making the Hope products available in Australia was "another key milestone in our commitment to bring the benefits of Hope to patients in global markets".
Zelira fell 0.1 cents or 1.3 percent to 7.8 cents with 14.5 million shares traded.

RHYTHM BIOSCIENCES

Rhythm says it has added Sydney's Northern Beaches Clinical Research as the seventh trial site in its Colostat trial for colorectal cancer, with Dr Anthony McGirr appointed the principal investigator and the first patient had been recruited.
Rhythm was up half a cent or 2.3 percent to 22 cents.

OPTHEA

Opthea says it has received $8,533,123 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Opthea said the rebate related to expenditure for the year to June 30, 2020.
Opthea fell six cents or 2.5 percent to $2.32 with 987,797 shares traded.

ACTINOGEN MEDICAL

Actinogen says it has received $2,883,584 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Actinogen said the rebate related to expenditure for the year to June 30, 2020.
Actinogen was unchanged at 2.2 cents with 3.7 million shares traded.

ACRUX

Acrux says it has received $521,374 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Acrux said the rebate related to expenditure for the year to June 30, 2020.
Acrux fell half a cent or 2.8 percent to 17.5 cents.

COGSTATE

Cogstate says its annual general meeting passed all resolutions, with 13,867,926 votes (18.68%) opposed to the remuneration report and all other resolutions passed easily.
According to Cogstate's most recent Appendix 2A new issue announcement said the company had 170,121,664 shares on issue, meaning the votes against the remuneration report amount to 8.2 percent, sufficient to call extraordinary general meetings.
Cogstate was up 24 cents or 24.7 percent to $1.21.

BARD1 LIFE SCIENCES

Bard1 says its annual general meeting will vote to approve a 30-to-one consolidation of its shares.
Bard1 said that if the resolution was passed, its 2,394,530,384 shares would be reduced to 79,817,679 shares, representing a 97 percent reduction in shares on issue.
The company said that, if approved, the consolidation would take effect from November 27, 2020.
Bard1 said the meeting would vote to adopt its remuneration report, elect Prof Allan Cripps, Dr Geoffrey Cumming and Helen Fisher as directors and approve the 10 percent placement capacity.
The meeting will be held on November 26, 2020 at 4pm (AEDT) virtually at https://web.lumiagm.com.
Bard1 fell 0.2 cents or 7.4 percent to 2.5 cents with 1.1 million shares traded.

SUDA PHARMACEUTICALS

Suda says its annual general meeting will vote to issue 3,000,000 options to director Dr Michael Baker.
Suda said the options would be exercisable at 5.5 cents, 6.5 cents and 7.5 cents within three years, vesting in three equal tranches immediately upon issue, 12 months from the issue date and 24 months from the issue date.
The company said the meeting would vote to adopt the remuneration report, re-elect David Simmonds as a director, ratify the prior issue of shares and options, amend its constitution, approve the 10 percent placement capacity and approve the employee share option plan.
The meeting will be held on November 26, 2020 at 11am (AEDT) virtually at: https://www.advancedshare.com.au/Dashboard/Virtual-Meeting-Centre-Login.
Suda fell 0.1 cents or 2.4 percent to four cents with 1.1 million shares traded.

OPTISCAN IMAGING

Optiscan says investors will vote to issue up to 35,737,875 options to executive chairman Darren Lurie, Orchid Capital Investments and unrelated investors.
Optiscan said its annual general meeting would vote to issue up to 6,000,000 options to Mr Lurie, exercisable at 15 cents vesting in four equal tranches between May 31, 2021 and November 30, 2022, and expiring between November 30, 2024 and May 31, 2026.
The company said it would vote to issue up to 22,371,250 options to Orchid Capital and up to 7,366,625 options to unrelated sophisticated and professional investors, exercisable at 15 cents within 30 months.
Optiscan said the meeting would vote to adopt its remuneration report, re-elect Mr Lurie as a director, ratify the prior issue of shares, approve a 10 percent placement facility and to renew a proportional takeover provision in its constitution.
The meeting will be held on November 26. 2020 at 11am (AEDT) virtually and to register, email the company secretary: jmouchacca@optiscan.com.
Optiscan fell 0.2 cents or two percent to 9.8 cents with 1.3 million shares traded.

EMVISION MEDICAL DEVICES

Emvision says its annual general meeting will vote to grant up to 1,500,000 options to chief executive officer Dr Ron Weinberger and non-executive director Dr Philip Dubois.
Emvision said the 1,000,000 options for Dr Weinberger would be exercisable at $1.25 by May 6, 2023, with half vesting on May 6, 2021 and half vesting on May 6, 2022.
The company said Dr Dubois' 500,000 options would be exercisable at $3.95 by September 29, 2023, vesting on September 29, 2021 and September 29, 2022.
Emvision said the meeting would vote to adopt its remuneration report, re-elect Dr Dubois and Geoff Pocock as directors, amend the employee securities incentive plan, ratify the prior issue of shares and to approve the 10 percent placement capacity.
The meeting will be held at BDO Office, Level 10, 12 Creek Street, Brisbane on November 26, 2020 at 1pm (AEST).
Emvision fell three cents or 1.05 percent to $2.84.

NUHEARA

Nuheara says its annual general meeting will vote to issue up to 3,000,000 options each to chief executive officer Justin Miller and executive director David Cannington.
Nuheara said the options would be exercisable at 2.5 cents by August 21, 2023 and would vest in three equal tranches immediately upon issue and on August 21, 2021 and 2022.
The company said investors would vote to issue 20 percent salary sacrifice shares of up to 681,818 shares or $15,000 to chair Cheryl Edwardes and up to 590,909 shares or $13,000 to director Kathryn Foster.
Nuheara said it would vote to issue 10 percent salary sacrifice shares of up to 1,850,909 shares or $40,720 to Mr Miller and up to 1,425,727 shares or $31,366 to Mr Cannington.
The company said the meeting would vote to adopt its remuneration report, elect Ms Edwardes, Warwick Sauer and Mr Cannington as directors and approve a 10 percent placement capacity
The meeting will be held at 190 Aberdeen Street, Northbridge Western Australia on November 27, 2020 at 9am (AWST).
Nuheara fell 0.4 cents or 8.3 percent to 4.4 cents with 12.4 million shares traded.

GENETIC SIGNATURES

Karst Peak Capital and Adam Leitzes say they have ceased to be substantial shareholders in Genetic Signatures.
In August, Karst Peak and Mr Leitzes said they had reduced their holding in Genetic Signatures to 15,934,528 shares or 11.17 percent (BD: Aug 7, 2020).
Today, Karst Peak and Mr Leitzes said that between October 13 and 23, 2020 they sold 15,934,528 shares for $30,080,383 or $1.89 a share.
In 2018, Karst Peak and Mr Leitzes became substantial in Genetic Signatures, acquiring 18,934,528 shares (18.20%) at 57 cents a share (BD: Nov 22, 2018).
Genetic Signatures fell three cents or 1.5 percent to $1.97.