Biotech Daily

Thursday November 16, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: OPTHEA UP 7.6%; DIMERIX DOWN 12.5%**

*** CERTA FT011 60% 'IMPROVEMENT IN SCLERODERMA PATIENTS'**

*** MONASH UNI: LYT-300 'REDUCES STRESS' FOR SOCIAL ANXIETY**

*** BURNET LICENCES STELLABODY TO ARGENX**

*** WEHI APPOINTS PROF KEN SMITH DIRECTOR**

*** WEHI: PANKIND $100k FOR PANCREATIC CANCER TEST**

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*** ALTERITY ATH434 'PRESERVES OXYGEN-LOSS CELL FUNCTION, IN-VITRO'**

*** MACH7 AGM: 31% OPPOSE DIRECTOR OPTIONS**

*** EMYRIA AGM 18% OPPOSE REMUNERATION REPORT**

*** ISLAND: 90% REVERSE VOTE, DELIVER REMUNERATION REPORT 1st STRIKE**

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*** ANTISENSE AGM 13% OPPOSE 'PERCHERON' NAME CHANGE**

*** NOXOPHARM RECEIVES $6.1m FEDERAL R&D TAX INCENTIVE**

*** THORNEY, TIGA TAKE 49% OF VISIONEERING**

*** REGAL INCREASES, DILUTED TO 10.6% OF VISIONEERING**

*** PLATINUM INCREASES, DILUTED TO 17.5% IN ADALTA**

*** RHYTHM LOSES CFO PAUL SMITH; DR TREVOR LOCKETT NON-EXECUTIVE**

MARKET REPORT

The Australian stock market fell 0.67 percent on Thursday November 16, 2023, with the ASX200 down 47.5 points to 7,058.4 points. Thirteen of the Biotech Daily Top 40 stocks were up, 18 fell, six traded unchanged and three were untraded.

Opthea was the best, up 2.5 cents or 7.6 percent to 35.5 cents, with 489,033 shares traded, followed by 4D Medical up 7.5 percent and Impedimed up 7.4 percent. Pharmaxis climbed 6.9 percent; Clinuvel and Volpara improved more than four percent; Immutep was up 3.5 percent; Cyclopharm rose 2.35 percent; Next Science and Resmed were up more than one percent; with Emvision, Neuren, Pro Medicus and SDI up less than one percent.

Dimerix led the falls, down two cents or 12.5 percent to 14 cents, with eight million shares traded. Cynata and Prescient lost more than 10 percent; Imugene was down 7.6 percent; Actinogen, Atomo and Genetic Signatures fell more than four percent; Avita, Medical Developments, Nova Eye and Starpharma lost more than three percent; Nanosonics and Telix shed more than two percent; Antisense, Mesoblast, Paradigm and Polynovo fell more than one percent; with Cochlear, CSL and Proteomics down less than one percent.

CERTA THERAPEUTICS

Certa says its 30-patient, phase II trial shows that 400mg oral FT011 had a “clinically meaningful improvement” in 60 percent of systemic scleroderma patients (p = 0.019).
Certa said the double-blinded trial recruited 30 adults randomly assigned to three treatment arms, either 400mg of FT011, 200mg of FT011 or a placebo once daily, in addition to standard-of-care, for 12 weeks.
The company said the trial showed treatment led to “significant improvements across multiple efficacy measures” and was safe and well tolerated with improvements in patients with scleroderma compared to placebo in both treatment arms after 12 weeks.
Certa said the results of the trial included a 60 percent improvement in patients treated with 400mg of FT011 and a 20 percent improvement in patients treated with a 200mng dose, compared with 10 percent in the placebo group.
Certa said the study had no differences in adverse event rates between the treatment arms and that there were no serious adverse events reported in the study or in study drug interruption, withdrawal or discontinuation.
The company said analysis of skin biopsy samples investigating changes to gene signatures showed that the systemic fibrotic disease gene signature was “modulated after 12 weeks, with an increased fibrosis signature score in the placebo group but significantly, a decrease in the same fibrosis signature score following FT011 400mg treatment”.
Certa said this gene signature analysis suggested that FT011 “may have a positive effect for scleroderma patients by reducing the inflammation and fibrosis associated with the disease”.
Certa chief executive officer Prof Darren Kelly said scleroderma was “a debilitating and life-threatening condition, and extremely complex in the way that the disease manifests itself in patients”.
“As the biological mechanism by which FT011 works precisely targets the root cause of fibrosis, we believe that FT011 is notably differentiated from previously unsuccessful clinical candidates,” Prof Kelly said.
The company said the trial was continuing in a subset of patients who had elected to remain on FT011 400mg treatment for up-to an additional 24 months.
Certa said early results from the extended subset group showed treatment continued to be safe, with clinical benefit observed for more than 19 months of therapy.
Certa said data from the trial titled ‘FT011 for the Treatment of Systemic Sclerosis. Results from a Phase II Study’ was presented at the American College of Rheumatology meeting in San Diego, California from November 10-to-15, 2023, and available at https://acrjournals.onlinelibrary.wiley.com/doi/epdf/10.1002/art.39501.
The company said it was planning a pivotal clinical trial of FT011, with the clinical trial design and development plans to be discussed with the US Food and Drug Administration in “early 2024” and the trial expected to begin in “late 2024”.
“We are pleased to have these exceptional clinical trial results presented to the scientific community … with FT011 demonstrating clinically important differences in multiple efficacy measures on top of standard-of-care in a short treatment timeframe,” Prof Kelly said.
“It is imperative that effective, safe, and well-tolerated therapeutics are efficiently developed, and which are truly beneficial for a scleroderma patient's quality of life,” Prof Kelly said.
“With the benefit of input from world-leading experts in the field, we are highly focused on advancing the clinical development program for FT011 towards the pivotal efficacy study,” Prof Kelly said.
Certa is a private company.

MONASH UNIVERSITY

Monash University says its 80-participant, phase IIa trial of oral LYT-300 for social anxiety shows the drug had a “statistically significant reduction in stress hormone responses”.

In June, Monash University said it had begun a 50-volunteer, phase IIa, placebo-controlled, proof-of-concept trial of LYT-300 with LYT-300 licencee, Boston’s Puretech Health, for social anxiety with results expected by the end of the year (BD: Jun 22, 2023).

Today, the University said the randomized, placebo-controlled trial was designed to evaluate the response of salivary cortisol, a hormone that managed stress, with the Trier social stress test (TSST) in healthy volunteers treated with either LYT-300 or placebo.

Monash said the trial achieved its primary goal of a statistically significant reduction versus placebo in the peak levels of cortisol in saliva ($p = 0.0001$).

The University said LYT-300 was based on an endogenous neuro-steroid and had different pharmacology to traditional benzodiazepines and showed a similar effect size to previously observed results for alprazolam, a benzodiazepine drug indicated for treatment of anxiety disorders, when assessed following the TSST procedure.

Monash researcher and developer of LYT-300 Prof Chris Porter said the treatment had been recognized for “its potential to treat a range of neurological and neuro-psychiatric indications and has a well-established rapid onset of action in mood disorders”.

“Historically there have been major hurdles associated with the development of endogenous neuro-steroids as medicines,” Prof Porter said. “Most notably, a lack of oral bioavailability and a need to administer intravenously.”

“This makes convenient dosing to patients over an extended period of time in chronic diseases extremely difficult,” Prof Porter said.

“These data validate that LYT-300 has the potential to become a simple oral capsule for people living with anxiety, a condition where there’s been a dearth of innovation,” Prof Porter said. “LYT-300, a non-benzodiazepine neurosteroid, blunts this stress response, highlighting its novel pharmacology and potential for helping patients in serious need of new treatment options.”

BURNET INSTITUTE

The Burnet Institute says it has licenced its Stellabody platform for developing biologic and antibody therapeutics to the Amsterdam-based Argenx.

The Burnet Institute said the research licence and option agreement gave Argenx the “option to take an exclusive licence to a limited number of molecular targets for Stellabody therapeutics”.

The Institute said Stellabody provided a tool for bio-therapeutic companies to help create drug candidates with greater efficacy that was based on a single modification buried within the antibody Fc, which transformed the potency of monoclonal antibodies and antibody-like biologics to increase monoclonal antibody potency by up-to 100-fold.

The Burnet Institute said Stellabody could confer new properties on monoclonal antibodies and related biologics to overcome lack of potency, increase cell responses induced by biologics where signaling was limiting and reduce the dose volume needed, thereby lowering the cost of goods and pricing.

The Institute said the platform could be tailored for several purposes, including “signal amplification, complement killing and target neutralization, with potential use in indications such as cancer, infection, autoimmunity and inflammation”.

The Institute said it had granted Argenx a non-exclusive research licence to explore the potential of Stellabody with the option of an exclusive commercial licence to a limited number of molecular targets, but did not state the commercial terms.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

WEHI says Prof Ken Smith has been appointed as its director, effective from May 2024.
The Walter and Eliza Hall Institute said that its president Jane Hemstritch made the announcement and Prof Smith would start work after returning from the UK, where he has been the head of Cambridge University's Department of Medicine since 2010.
The Institute said that Prof Smith was its seventh director in its 108-year history.
WEHI said that Prof Smith had scientific research links in Hong Kong, Singapore, Korea and Africa, with long-standing connections in Europe and the US.
The Institute said that Prof Smith had been "instrumental in forming alliances between industry and academia and … founding start-up companies and [had] commercial experience with the pharmaceutical industry in the UK, US and Europe.
WEHI said Prof Smith completed his Doctor of Philosophy at the Institute through the University of Melbourne, supervised by former director, Prof Gustav Nossal and Prof David Tarlinton.
The Institute said Prof Smith held a Bachelor of Medicine and Bachelor of Surgery from the University of Melbourne and a Doctor of Science from the University of Cambridge.
WEHI said that his laboratory at Cambridge University ran "an experimental medicine and translational program focused on understanding the mechanisms underlying immune-mediated diseases" and Prof Smith was the director of the Cambridge Institute for Therapeutic Immunology and Infectious Disease.
The Institute said that Prof Alan Cowman continued as acting director.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

WEHI says it has a $100,000 grant from the Australian Pancreatic Cancer Foundation, Pankind, to develop an early blood test for pancreatic cancer.
WEHI said it hoped the test would, for the first time, identify patients with early stages of pancreatic cancer, which was "a crucial step towards improving survival rates and quality of life for patients".
The Institute said the project was based on its discovery of proteins that could identify early pancreatic cancer in patients.
WEHI said researchers would use its 'Purple' Pancreatic Cancer Translational Registry, database on the treatment of patients at 48 cancer centers in Australia, New Zealand and Singapore, with more than 4,000 patients and 2,000 bio-specimens currently available.
WEHI said data from the registry confirmed that 70 percent of patients presented with advanced disease, highlighting the need for biomarkers to enable earlier detection.
The Institute said researchers hoped the test could be used by general practitioners and oncologists for early intervention to enable more effective treatment options for patients.
WEHI consultant medical oncologist and project lead Dr Belinda Lee said the grant would help the team translate their findings into a diagnostic test.
"We have identified 13 proteins that could distinguish between the early and late stages of pancreatic ductal adenocarcinoma, the most common type of pancreatic cancer that's fast-becoming the cancer of our generation," Dr Lee said.
"While the five-year survival rate of most other cancers has improved, the incidence and death rate from [pancreatic ductal adenocarcinoma] is rising, and it's projected to become the second leading cause of cancer-related death by 2030," Dr Lee said.
"Even with a diagnosis, there are no biomarkers that can guide clinical decisions for pancreatic cancer, meaning clinicians have limited opportunities to ensure the right, and best, treatment for their patients," Dr Lee said. "We hope to validate these proteins and show that they can be used to reliably screen for early pancreatic cancer," Dr Lee said.

ALTERITY THERAPEUTICS

Alterity says a laboratory model of ATH434 for neurodegenerative disorders shows it can "preserve mitochondrial function after oxidative injury".

Alterity said the results were presented in a poster, titled 'Potent Antioxidant and Mitochondrial-protectant Effects of ATH434, a Novel Inhibitor of alpha-Synuclein Aggregation with Moderate Iron-binding Affinity' at the Society for Neuroscience in Washington DC, from November 11 to 15, 2023.

The company said the study investigated the efficacy of ATH434 compared to other agents "as mitochondrial protectants using a menadione-induced model of oxidative stress in a neuronal cell line".

Alterity said the data indicated ATH434 could exert direct anti-oxidant activity independent of its iron binding properties, a feature which was "not observed with another iron binding agent approved for treating iron overload that was also investigated".

The poster concluded "that anti-oxidant activity may be an important contributor to the efficacy of ATH434 in neuro-degenerative disorders characterized by excess labile central iron, thus enhancing the efficacy of its moderate iron binding".

Alterity managing-director Dr David Stamler said the data underscored "the potential of ATH434 as a treatment for neuro-degenerative diseases, including Parkinson's disease and related disorders".

"We have long known that ATH434 is able to reduce labile iron which, when elevated, can drive oxidative stress," Dr Stamler said. "The demonstrated mitochondrial protection may reveal additional mechanisms that augment its ability to slow disease progression."

Alterity was unchanged at 0.7 cents with one million shares traded.

INCANNEX HEALTHCARE

Incannex says the Federal Court of Australia has approved its scheme of arrangement to redomicile to the US and delist from the ASX, effective on November 28, 2023

In July, Incannex said it intended to redomicile to the US (BD: Jul 10, 2023).

Today, the company said its last date of trading on the ASX was tomorrow, and it would delist from the ASX and be admitted onto the Nasdaq on November 29, 2023.

Incannex fell 1.2 cents or 20.7 percent to 4.6 cents with 27.5 million shares traded.

MACH7 TECHNOLOGIES

Mach7 says its annual general meeting passed all resolutions, but the issue of options to directors Robert Bazzani and Dr Eliot Siegel faced up-to 31 percent opposition.

Last month, Mach7 said shareholders would vote to issue Mr Bazzani and Dr Siegel 25,000 options each (BD: Oct 17, 2023).

Today, the company said the resolutions to approve the issue of options to Mr Bazzani was opposed by 35,336,176 votes (30.92%), with 78,931,548 votes (69.08%) in favor, with Dr Siegel's options opposed by 35,336,676 votes (30.64%).

Mach 7 said the remuneration report, amendments to its constitution, the 10 percent placement capacity and the issue of managing-director Mike Lampron's shares and options were opposed by between 15.68 percent and 18.04 percent of votes.

The company said the three remaining resolutions were all passed overwhelmingly.

According to its most recent notice, Mach7 had 240,866,047 shares on issue, meaning that the votes against Mr Bazzani's options amounted to 14.7 percent of the company, sufficient to requisition extraordinary general meetings.

Mach7 was up one cent or 1.4 percent to 72 cents.

EMYRIA

Emyria says its annual general meeting passed all resolutions with the remuneration report opposed by 18.01 percent of the meeting.
Emyria said the remuneration report was approved by supported by 109,874,021 votes (81.99%) and opposed by 24,130,042 votes (18.01%).
The company said all other resolutions were passed by more than 99.86 percent.
According to its most recent notice, Emyria has 366,129,396 shares on offer, meaning that the votes against the remuneration report amounted to 6.6 percent of the company, sufficient to requisition extraordinary general meetings.
Emyria was unchanged at 7.5 cents.

ISLAND PHARMACEUTICALS

Island says its annual general meeting overwhelmingly passed all resolutions except the adoption of its remuneration report, which faced 90.41 percent dissent.
Island said that initially, the remuneration report proxy votes had 14,159,231 votes (99.98%) in favor with 2,941 votes (0.02%) against, but when the poll was taken, the report was opposed by 12,804,714 votes (90.41%) with 1,357,458 votes (9.59%) in favor.
Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and if passed the directors must stand for re-election within 90 days.
The company said the 10 percent placement capacity was opposed by 271,000 votes (1.40%) with all other resolutions passed unopposed.
According to its annual report, Island had 81,268,468 shares on offer, meaning that the 12,804,714 votes against the remuneration report amounted to 15.8 percent of the company, sufficient to requisition extraordinary general meetings.
Island fell 0.1 cents or 1.3 percent to 7.7 cents.

RADIOPHARM THERANOSTICS

Radiopharm says its annual general meeting passed all resolutions, with up-to 24.8 percent opposition to director options.
Last month, Radiopharm said it would issue 7,426,895 options to chief executive officer Riccardo Canevari, 1,235,761 options to chair Paul Hopper and 1,451,012 options to director Ian Turner, exercisable at 11.2 cents each (BD: Oct 18, 2023).
Today, the company said Mr Turner’s options were opposed by 11,895,094 votes (24.81%) with 36,048,688 votes (75.19%) in favor.
Radiopharm said Mr Hopper and Mr Canevari’s options were opposed by 24.76 percent and 23.64 percent of votes, respectively.
The company said the remuneration report and the issue of securities under its employee incentive plan had 22.49 percent and 24.77 percent opposition, respectively.
The company said the re-election of director Dr Michael Baker, the 10 percent placement capacity and the amendment to its constitution, passed by wider margins.
According to its annual report, Radiopharm has 339,313,037 shares on issue, meaning that the 11,895,094 votes against Mr Turner’s options amounted to 3.5 percent of the company, not sufficient to requisition extraordinary general meetings.
Radiopharm fell 0.4 cents or 5.1 percent to 7.5 cents.

ANTISENSE THERAPEUTICS

Antisense says its annual general meeting passed all resolutions but with up-to 13 percent opposition to the resolution to change its name to ‘Percheron Therapeutics’.
Last month, Antisense said the name change positioned it for its intended future as an “international participant in the field of rare diseases” with Percheron “a breed of draft horse known for their strength, intelligence, adaptability and resolve” (BD: Oct 17, 2023).
Today, the company the special resolution to approve the name change was opposed by 43,135,780 votes (13.09%) opposition, with 287,724,548 votes (86.96%) in favor.
Antisense said all other resolutions passed with 3.55 percent to 9.69 percent dissent.
According to its annual report, Antisense had 901,544,971 shares on issue, meaning that the 43,135,780 votes against the name change amounted to 4.8 percent of the company, not sufficient to requisition extraordinary general meetings.
Antisense fell 0.1 cents or 1.6 percent to 6.1 cents.

NOXOPHARM

Noxopharm says it has received about $6,052,000 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Noxopharm said the rebate related to research and development expenditure for the year to June 30, 2023.
Noxopharm was up 1.5 cents or 12 percent to 14 cents.

VISIONEERING TECHNOLOGIES

Melbourne’s Thorney, Tiga Trading and related parties say they have increased in Visioneering from 11,958,626 shares (38.17%) to 25,209,833 shares (49.15%).
Thorney and Thorney Investment Group Australia (Tiga), said that with the Waislitz Family Foundation and Jasforce Pty Ltd, between December 6, 2022 and November 13, 2023 they bought and sold shares on market, converted a note and subscribed for 6,669,908 shares in a rights issue for $1,467,380, or 22 cents a share.
On Monday, Visioneering said it raised $2.4 million of a hoped-for $3.9 million in its five-for-nine rights offer at 22 cents per Chess depository interest (BD: Nov 13, 2023).
Visioneering fell 1.5 cents or 6.7 percent to 21 cents.

VISIONEERING TECHNOLOGIES

Regal Funds Management Pty Ltd says it has increased and been diluted in Visioneering from 4,329,413 shares (13.82%) to 5,486,357 shares (10.63%).
The Sydney-based Regal Funds said between April 19 and November 13, 2023 it bought and sold shares on the market, with a total purchase of 1,752,003 shares for $419,000, or 23.9 cents a share, and was diluted in capital raising (see above).

ADALTA

Platinum Asset Management says it has increased and been diluted in Adalta from 87,863,591 shares (19.90%) to 87,863,759 shares (17.47%).
The Sydney-based Platinum said on July 14, 2023 it acquired 168 shares at no cost.
Earlier this month, Adalta said it had raised $1.65 million of a hoped-for $1.23 million in an “oversubscribed placement” at two cents a share (BD: Nov 7, 2023).
Adalta was up 0.1 cents or 5.3 percent to two cents.

RHYTHM BIOSCIENCES

Rhythm says chief financial officer and joint company secretary Paul Smith “has resigned for personal reasons, by mutual agreement”.

Rhythm said technical director and former managing-director Dr Trevor Lockett would become a non-executive director, effective from December 15, 2023.

The company said financial controller Guy Carisbrooke would assume financial duties.

Rhythm said Andrea Steele would continue as sole company secretary, it had commenced the search for a chief executive officer, and that following a handover period, executive chair Otto Buttula would “relinquish his executive duties”.

Rhythm fell two cents or 10 percent to 18 cents.