Biotech Daily

Thursday April 15, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ACTINOGEN UP 27%; OSPREY DOWN 14%**

*** ALCIDION RAISING $18m FOR $9.6m EXTRAMED; $21m DEFENCE DEAL**

*** AMPLIA COMPLETES PHASE I AMP945 DOSING**

*** RACE: BISANTRENE INHIBITS FTO CANCER - INDEPENDENT STUDY**

*** CLARITY DOSES 1st PATIENT IN PHASE II CU64-SARTATE TRIAL**

*** VICTORIA $2.4m FOR BONE MARROW SYNDROME RESEARCH**

*** ACRUX FILES DAPSONE FOR ACNE ANDA TO FDA**

*** RECCE: R327 FOR BURNS ADDED TO TRIAL REGISTRY**

*** UNIVERSAL BIO: WINE & BEER SENTIA WINE TEST US DISTRIBUTOR**

*** TOTAL BRAIN ADDS HEART VARIABILITY TO MENTAL HEALTH MONITOR**

*** ELIXINOL NAME CHANGE, 43% DIRECTORS FEE HIKE AGM**

*** MITSUBISHI, MORGAN STANLEY TAKE 5% OF CYCLOPHARM**

*** CREDIT SUISSE TAKES 5% IN IDT**

*** MERCER STREET REDUCES TO 5% IN ANTERIS**

MARKET REPORT

The Australian stock market was up 0.51 percent on Thursday April 15, 2021, with the ASX200 up 35.5 points to 7,058.6 points. Eighteen of the Biotech Daily Top 40 stocks were up, 14 fell and eight traded unchanged.

Actinogen was the best on no news, up 1.2 cents or 27.3 percent to 5.6 cents, with 54.2 million shares traded. Orthocell climbed 9.3 percent; Resonance rose 5.3 percent; Amplia was up 4.4 percent; Compumedics, LBT and Pharmaxis were up more than three percent; Antisense, Imugene, Neuren and Universal Biosensors improved more than two percent; Avita, Clinuvel and Paradigm were up more than one percent; with CSL, Mesoblast, Polynovo, Proteomics and Telix up by less than one percent.

Osprey led the falls, down 0.3 cents or 14.3 percent to 1.8 cents, with 54.0 million shares traded. Uscom lost 6.1 percent; Kazia and Next Science fell more than four percent; Impedimed and Genetic Signatures were down more than three percent; Opthea shed 2.2 percent; Cyclopharm, Cynata, Nanosonics and Volpara were down more than one percent; with Cochlear, Medical Developments, Pro Medicus, Starpharma and Resmed down by less than one percent.

ALCIDION GROUP

Alcidion says it has placed $15.4 million at 32 cents a share to buy Extramed, hopes a share plan will raise $2.5 million, and has a $21 million Australian Defence contract.
Alcidion said it paid GBP5.3 million ($A9.6 million) for Extramed, a UK provider of patient flow management software with nine UK National Health Service (NHS) Trusts.
The company said the acquisition included six new NHS Trusts as customers for Alcidion, which expanded its UK presence to 27 NHS Trusts, and was expected to contribute revenue of $2.7 million in 2021-'22, "based solely on existing contracts".
Alcidion said that prior to the acquisition, Extramed had a healthcare information technology agreement with Hitachi Consulting to build the UK's first fully-integrated, hospital-wide, digital command centre at Salford Royal NHS hospital, which would include its Miya Precision patient management platform.
Alcidion managing-director Kate Quirke said the "acquisition significantly strengthens our position in the UK and signals our commitment to this very important market".
"We are delighted to welcome the highly experienced Extramed team of 11 staff, as well as new customers, as we continue to transform the delivery of healthcare with smart technology solutions," Ms Quirke said.
Alcidion said the institutional placement share price was a 6.7 percent discount to the five-day volume weighted average price.
The company said the share plan record date was April 14, with the plan opening on April 22 and closing on May 5, 2021.
Alcidion said that Henslow Pty Ltd was the financial advisor to the acquisition and lead manager to the placement, with Bell Potter Securities acting as co-manager.
Separately, Alcidion said it had an up-to $21 million, five-and-a-half-year contract with the Australian Department of Defence for its Miya Precision patient management platform.
Alcidion said that it had been selected as a preferred provided to the Defence Department's Healthcare Knowledge Management (HKM) project which aimed to develop a system that recorded, stored, aggregated and analysed health information.
Alcidion said it was part of a consortium of information technology and engineering firms and the contract was for stage one of two stages of the HKM project, providing its Miya platform as the longitudinal health record to collect data.
Alcidion said the contract was being finalized and the project was expected to begin by December 31, 2021.
Alcidion was up three cents or 8.8 percent to 37 cents with 11.1 million shares traded.

AMPLIA THERAPEUTICS

Amplia says it has dosed all participants in its 64-subject, phase I trial of its focal adhesion kinase inhibitor AMP945 for cancer and fibrotic diseases.
Last year, Amplia said it had dosed the first healthy volunteer in the double blind, placebo-controlled, single and multiple-ascending dose safety trial of AMP945, following approval from Melbourne's Alfred Hospital (BD: Sep 8, Oct 8, 2020).
Last month, the company said it had completed the single-ascending dose portion of the trial (BD: Mar 17, 2021).
Today, Amplia said it had dosed all subjects in the single-ascending dose and multiple ascending dose cohorts with no tolerability concerns or dose-limiting adverse events.
The company said it would provide an analysis of the trial results by July 2021.
Amplia chief executive officer Dr John Lambert said the company planned "to commence phase II clinical trials in patients within the next 12 months".
Amplia was up one cent or 4.4 percent to 23.5 cents.

RACE ONCOLOGY

Race says University of Chicago researchers have shown that Bisantrene "is a highly effective inhibitor of the fat mass and obesity associated protein".

Last month, Race said that Bisantrene had been identified as an inhibitor of the fat mass and obesity associated protein (FTO) which was over-produced in metastatic melanoma cancers and essential to some kidney cancers (BD: Mar 19, 25, 2021).

Today, the company said that University of Chicago researchers Prof Chuan He and Prof Yu-Ying He led the research at the City of Hope Hospital and "identified that FTO plays a critical role in the development of skin cancers caused by low-level arsenic exposure, which promotes tumor growth".

Race said the study demonstrated "that Bisantrene-targeted inhibition of FTO limits the growth of these skin cancers in both cell culture and mice".

The research article, titled 'Autophagy of the m6A mRNA demethylase FTO is impaired by low-level arsenic exposure to promote tumorigenesis' was published in Nature Communications and is at: https://www.nature.com/articles/s41467-021-22469-6.

Race chief scientific officer Dr Daniel Tillett said the independent confirmation that Bisantrene targeted FTO and could treat skin cancer was "of great importance".

"Many scientists and pharmaceutical companies are skeptical of potential cancer breakthroughs until they have been replicated by an independent group of researchers," Dr Tillet said. "This new paper repeating the earlier FTO work of the City of Hope Hospital is a major step forward for our clinical plans for Bisantrene."

Race was up 24 cents or 7.8 percent to $3.30 with 1.045 million shares traded.

CLARITY PHARMACEUTICALS

Clarity says it has dosed the first participant in its 63-patient phase II 'Disco' trial of its Copper-64 Sartate imaging agent for neuroendocrine tumors.

Last year, Clarity said it had US Food and Drug Administration orphan drug status for Cu-64 Sartate as a diagnostic agent for neuroendocrine tumors (BD: May 20, 2020).

Today, the company said the diagnostic imaging, or Disco, trial used positron emission tomography on patients with known or suspected gastro-entero-pancreatic neuroendocrine tumors, to assess the potential of Cu-64 Sartate to diagnose tumors.

The company said the study would compare the diagnostic performance of Cu-64 Sartate after four and 20 hours to the current standard of care, gallium-68 Dotatate, at one hour.

Clarity said the trial was being conducted at three sites in Australia.

The company said neuroendocrine tumors were found in the predominantly found in the gastrointestinal tract and broncho-pulmonary tree, and less frequently in the pancreas, biliary tract, liver, ovaries and testes.

Clarity said that a delay in the diagnosis of neuroendocrine tumors was common, with about 30 percent to 74 percent of neuroendocrine tumor patients having distant metastases at the time of diagnosis.

Clarity chairman Dr Alan Taylor said that the 64-Cu Sartate first-in-human diagnostic trial in neuroendocrine tumors had demonstrated promising results in the safety and potential effectiveness of the product as a new way to detect neuroendocrine cancers".

"The study showed that the longer 12.7-hour half-life of Cu-64, combined with the stability of our proprietary SAR chelator which does not leak copper over time, proved to be advantageous in identifying additional tumor burden as it allows clinicians to have the flexibility to image patients at later time points than products based on Ga-68 or copper-based products that employ inferior chelators," Dr Taylor said.

Clarity is public unlisted company.

VICTORIA GOVERNMENT

The Victorian Government says it has provided $2.4 million to launch a Bone Marrow Biobank and support research into bone marrow failure syndromes.
A media release from the Minister for Innovation, Medical Research and the Digital Economy Jaala Pulford said that the biobank was an initiative of the Centre of Research Excellence in Bone Marrow Biology and Maddie Riewoldt's Vision, supported by $2.1 million from the Victorian Government.
Ms Pulford said the biobank facility would "collect thousands of tissue samples from patients to aid research and clinical trials and improve treatment options".
The media release said that bone marrow failure syndromes mainly affected people aged 17 to 40 years, with about 160 Australians diagnosed every year and more than 50 percent of those diagnosed dying from the syndromes.
Ms Pulford said the Victoria Government had provided $305,000 to the Victorian Cancer Agency for a new international fellowship to investigate links between bone marrow failure syndromes and cancer biology.
The State Government said that the Australian Marrow Failure Biobank would open in May at Biobanking Victoria in Clayton.

ACRUX

Acrux says the it has filed an abbreviated new drug application for the acne treatment, 7.5 percent Dapsone gel, to the US Food and Drug Administration for review.
Acrux said the applications was its fourth generic dossier.
The company said that Dapsone gel had annual sales of more than $US206 million.
Acrux said that the FDA had told it the submission was sufficiently complete to be accepted for review, and the reference drug was Aczone, marketed by the Exton, Pennsylvania Almirall LLC in the US.
Acrux was unchanged at 15 cents with 1.1 million shares traded.

RECCE PHARMACEUTICALS

Recce says its broad-spectrum synthetic antibiotic R327 for topical burns has been registered on the Australian New Zealand Clinical Trial Registry for a phase I/II trial.
In February, Recce said it was ready to start a 30-patient, phase I/II safety and efficacy trial of the spray-on formulation of its R327 for topical burns wound infections at Perth's Fiona Stanley Hospital (BD: Feb 16, 2021).
Today, the company said 10 patients would receive R327 daily for 14 days with 20 patients receiving R327 three times a week.
Recce was up six cents or 5.1 percent to $1.24 with 1.3 million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says it has appointed Wine & Beer Supply as a non-exclusive distributor of its Sentia wine sulphur dioxide analyzer platform in the US.
Universal Biosensors said the distribution agreement with the Ashland, Virginia-based Wine & Beers Supply spanned three years.
Universal Biosensors chief executive officer John Sharman said that Wine & Beer would "give Sentia greater access to the 11,500 wineries across the country".
Universal Biosensors was up two cents or 2.7 percent to 75 cents.

TOTAL BRAIN

Total Brain says it has included a heart rate variability function to its mental health self-monitoring and self-care smartphone application platform to detect stress.
Total Brain said that the heart rate variability technology could be used discretely or continuously and provided “personalized insights that can guide in-the-moment strategies to alleviate stress, support a restful night’s sleep and mentally prepare for the day ahead”.
The company said that pilot study results of the heart rate variability function showed a 25 percent reduction in chronic stress after three months of use.
Total Brain said the ‘discrete’ heart rate variability function was accessible through a smartphone camera or a wearable wrist device and would calculate stress in up-to two minutes with 90 percent accuracy, compared to a heart rate sensor chest strap.
The company said the continuous heart rate variability technology was licenced from Felix, based at England’s Cambridge University, and continuously measured stress using a Garmin wearable device, which would launch the by the end of the year.
Total Brain said heart rate variability function was “a significant revenue opportunity” and it estimated a material increase in the average price per user.
Total Brain was up two cents or 7.1 percent to 30 cents.

ELIXINOL GLOBAL

Elixinol says its annual general meeting will vote to change the company name to Elixinol Wellness and increase the directors’ fee pool by 42.9 percent to $500,000.
Elixinol said the name change was proposed to “better reflect the company’s vision of building a global, hemp-derived health and wellness consumer products business”.
The company said investors would vote to increase the pool of directors’ fees from $350,000 a year to $500,000 a year.
Elixinol said the meeting would vote to re-elect director Paul Benhaim, adopt the remuneration report, approve the equity plan, ratify and approve the previous issue of shares, and approve an additional 10 percent placement capacity.
The online meeting will be held on May 17, 2021 at 10am (AEST).
Elixinol was unchanged at 18 cents.

CYCLOPHARM

Mitsubishi, Morgan Stanley and its subsidiaries say they have become substantial in Cyclopharm with 5,072,994 shares or 5.43 percent of the company.
The Tokyo, New York, London and Sydney-based Morgan Stanley said that between January 19 and April 12, 2021 it bought, borrowed and received shares with the single largest purchase 4,500 shares for $12,825 or $2.85 a share.
Cyclopharm fell five cents or 1.9 percent to $2.55.

IDT AUSTRALIA

Sydney’s Credit Suisse Holdings says it has become a substantial shareholder in IDT with 12,004,390 shares or 5.00 percent of the company.
Earlier this month, Credit Suisse said it has ceased its substantial shareholding in IDT, after becoming substantial in March (BD: Mar 26, Apr 8, 2021).
Today, Credit Suisse said that between April 8 and 12, 2021, it bought and sold shares with the single largest purchase 989,144 shares for $374,162 or 37.8 cents a share.
IDT fell half a cent or 1.4 percent to 34.5 cents.

ANTERIS TECHNOLOGIES (FORMERLY ADMEDUS)

New York's Mercer Street Global Opportunity Fund says it has reduced its substantial holding in Anteris from 341,545 shares (5.20%) to 335,383 shares (5.06%).

Mercer Street said that between February 25 and March 25, 2021 it sold 61,545 shares for $647,334 or an average of $10.52 and on April 13, acquired 55,383 shares for $550,000 or $9.93 a share as part of a drawdown facility (BD: Apr 12, 2021).

In January, Anteris said it had $20 million in finance with Mercer including a $1 million and $1.5 million placement, a $1 million convertible note and a $16.5 million equity draw-down facility (BD: Jan 17, 2021).

Anteris was up 10 cents or one percent to $9.90.