Biotech Daily

Wednesday January 25, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ALCIDION UP 7%; COMPUMEDICS DOWN 10%**

*** COMPUMEDICS EXPECTS H1 REVENUE UP 7% TO $18m; LOST MEG DEAL**

*** EMVISION BRAIN SCANNER TRIAL 50% ENROLLED, $600k MILESTONE**

*** ALTERITY OPENS ITALY ATH434 MSA TRIAL SITE**

*** NOVA EYE 2RT TRIALS FOR CENTRAL SEROUS RETINOPATHY**

*** IMMURON RESPONDS TO FDA TRAVELAN CLINICAL HOLD**

*** MEDLAB WINS UK MARIJUANA NANABIS IMPORT CERTIFICATE**

*** ADALTA I-BODY 'POTENTIAL FOR OSTEOPOROSIS, IN-VITRO'**

*** RECCE RECEIVES $4.3m FEDERAL R&D TAX INCENTIVE; RADIUM LOAN**

*** CRESO REQUESTS 'DEBT RESTRUCTURE, ACQUISITION' TRADING HALT**

*** HARBOUR TAKES 14% OF VOLPARA**

*** MEURS TAKES 17% OF ADALTA; YUUWA**

*** COGSTATE LOSES DIRECTOR DAVID DOLBY**

MARKET REPORT

The Australian stock market fell 0.3 percent on Wednesday January 25, 2023, with the ASX200 down 22.1 points to 7,468.3 points. Nine of the Biotech Daily Top 40 stocks were up, 19 fell, nine traded unchanged and three were untraded.

Alcidion was the best, up one cent or 6.7 percent to 16 cents, with 1.2 million shares traded. Genetic Signatures climbed 4.2 percent; Antisense, Emvision, Micro-X and Volpara were up more than three percent; Clinuvel rose 2.8 percent; Cochlear was up 1.3 percent; with Opthea and Starpharma up by less than one percent.

Compumedics led the falls, down two cents or 10 percent to 18 cents, with 327,202 shares traded. Actinogen fell 4.2 percent; Atomo, Cyclopharm, Dimerix, Neuren and Patrys lost more than three percent; Polynovo shed 2.8 percent; Medical Developments, Nova Eye, Orthocell, Proteomics, Resmed, Resonance and Telix were down more than one percent; with Avita, CSL, Mesoblast, Nanosonics, Paradigm and Pro Medicus down by less than one percent.

COMPUMEDICS

Compumedics says it expects unaudited revenue for the six months to December 31, 2023 to be up 7.14 percent to $18.0 million, compared to the prior corresponding period.
Compumedics said its 2023 sales orders are “expected to be at least $40 million which is in line with the [annual general meeting] guidance”.
The company said it continued to “experience some ongoing global supply issues, chip shortages/delays and other pandemic related factors, which did constrain revenues in the first half … [and] continues to work to resolve these matters”.
Compumedics said the “first MEG sale to BNI will be removed due to the ongoing and protracted timing of resolving technical issues being outside what is acceptable to BNI”.
In 2019, the company said the installation of the Orion Lifespan magneto-encephalography (MEG) at the Barrow Neurological Institute (BNI) was the company’s “largest system contract” to date (BD: May 8, 2019).
Compumedics said at that time it was in the process of submitting a 510(k) clearance application to the US Food and Drug Administration to use the magneto-encephalography device for epilepsy and pre-surgical brain function mapping.
Compumedics fell two cents or 10 percent to 18 cents.

EMVISION MEDICAL DEVICES

Emvision says it has enrolled half of the 30 volunteers in its portable brain scanner trial, triggering a $600,000 milestone payment from the Australian Stroke Alliance.
Last year, Emvision said it had begun enrolment and scanning for the portable brain scanner trial at Sydney’s Liverpool Hospital (BD: Oct 4, Nov 30, 2022).
At that time, the company said the protocol was to be announced, but the first two stages would enrol at least 180 participants, including acute stroke and stroke mimic patients, with endpoints of verification, safety and data to “enhance artificial intelligence algorithms”.
Today, Emvision said that it expected to enrol all volunteers “in the coming weeks” and once completed, stage two of the trial would be activated and involve up to 150 acute stroke/stroke mimic patients.
The company said that it had triggered the milestone payment from the performance of its first and second-generation brain scanner devices in benchtop testing experiments.
Emvision chief executive officer Dr Ron Weinberger said the company was “pleased that our trial is progressing as planned”.
“We have strong clinical engagement and the ease of training and use of our device, along with the speed of scanning, has certainly helped with the process,” Dr Weinberger said. “The testing conducted as part of our ASA milestones has shown encouraging benchtop results from our system enhancements which bodes well for our clinical trials.”
Emvision was up six cents or 3.5 percent to $1.76.

ALTERITY THERAPEUTICS

Alterity says it has opened enrolment in Italy for its 60-patient, phase II, randomized, double-blind, placebo-controlled trial of ATH434 for multiple system atrophy (MSA).
In 2022, Alterity said it had begun the study of early-stage multiple system atrophy in Sydney, exploring the efficacy of ATH434 on neuro-imaging and protein biomarkers as well as characterization of safety and pharmaco-kinetics (BD: Sep 20, Oct 13, 2022).
Today, the company said patients would receive one of two dose levels of ATH434 or placebo for 12 months, and the data would inform the design of a phase III study.
Alterity was up 0.1 cents or 10 percent to 1.1 cents.

NOVA EYE MEDICAL

Nova Eye says studies in Australia and Canada are assessing the safety and efficacy of its retinal rejuvenation therapy (2RT) laser for central serous retinopathy.

Nova Eye said that the Melbourne Centre for Eye Research Australia and Toronto Retinal Institute studies of its sub-threshold nano pulse 2RT for central serous retinopathy were investigator-initiated.

Last year, Nova Eye said it had recruited the investigator sites for its confirmatory pivotal study of its retinal rejuvenation therapy (2RT) for age-related macular degeneration and in August said most of its $13.4 million revenue came from sales by its glaucoma consumable surgical devices division (BD: Aug 26; Oct 24, 2022).

Today, the company said that central serous retinopathy was the fourth most common retinal disease, occurring when fluid built-up under the retina, resulting in sudden central vision loss or distortion, with males in their 30s to 50s more likely to develop it.

Nova Eye said the estimated market for 2RT for central serous retinopathy was about $US60 million ($A84.5 million) a year.

The company said that current treatment options for central serous retinopathy were limited to thermal laser therapy and photodynamic therapy which had good efficacy but high risk, while “the unique method of action of 2RT that stimulates rejuvenation of the retinal pigment epithelium makes therapy with 2RT potentially better for patients with [central serous retinopathy]”.

Nova Eye said the trial at the Toronto Retinal Institute would investigate the role of 2RT for acute central serous retinopathy and had recruited 25 patients, to date.

The company said that the trial at the Centre for Eye Research Australia, with Prof Wilson Heriot from Melbourne’s Retinology Institute Glen Iris would investigate the role of 2RT for acute chronic central serous retinopathy and had recruited 10 patients.

Prof Heriot said that “2RT has a unique method of action that does not cause damage to the retina” which in young central serous retinopathy patients was very important.

Nova Eye said it expected results in about 12 months’ time.

Nova Eye fell half a cent or 1.9 percent to 26 cents.

IMMURON

Immuron says it has filed a response letter to the US Food and Drug Administration clinical hold on Campetec for Campylobacter and enterotoxigenic Escherichia coli (ETEC).

Last year, Immuron said the US FDA responded to its investigational new drug application for a trial of the cow colostrum-based polyclonal antibody for Campylobacter enterotoxigenic Escherichia coli saying it did not “contain sufficient information” and placed the application on a clinical hold (BD: Jul 26, 2022).

In May, Immuron said the US Naval Medical Research Centre (NMRC) had applied for two 30-volunteer trials of the treatment, known as Campetec, for campylobacteriosis and enterotoxigenic Escherichia coli-induced diarrhoea (BD: May 11, 2022).

Today, the company said that the investigators from Johns Hopkins University Bloomberg School of Public Health in Baltimore, Maryland, and personnel from the US Naval Medical Research Center met with the FDA in December, to discuss the clinical hold and advise on a path forward to address the safety concerns and supporting data associated with the new product.

Immuron said that with its collaborators it had addressed the specific concerns of the FDA in its response letter and expected the FDA to provide feedback within 30 days.

Immuron was up 0.1 cents or 1.2 percent to 8.2 cents.

MEDLAB CLINICAL

Medlab says it has an Import Certificate from the UK Home Office for its one-to-one tetrahydrocannabinol (THC) and cannabidiol (CBD) Nanabis oral spray.
In 2022, Medlab said it had UK Medicines and Healthcare Product Regulatory Agency approval for the marijuana-derived Nanabis, which would have the alternative name of Nanadol in the UK (BD: Nov 25, 2022).
Today, the company said that it was applying for export certification from Canberra, which could take up to 28 days and would allow for the lawful shipment of Nanabis to the UK.
Medlab chief executive officer Dr Sean Hall said “it’s great to be able to expand the successes we have had with Nanabis to the UK people”.
Medlab was up 40 cents or 5.2 percent to $8.10.

ADALTA

Adalta says an in-vitro study has shown “the broad applicability of the i-body platform,” and suggested its potential for the treatment of osteoporosis.
Adalta previously said that i-bodies were named from the “intermediate” of four groups of immunoglobulin or immunoglobulin-like domains.
Today, the company said the article, titled ‘ADR3, a next generation i-body to human RANKL, inhibits osteoclast formation and bone resorption,’ was published in the Journal of Biological Chemistry, led by Prof Jiake Xu and the full article was available at: https://doi.org/10.1016/j.jbc.2023.102889.
Adalta said the study showed that the i-body ADR3 binds to the RANKL cell membrane protein and was capable of inhibiting “a wide range of cell signaling pathways controlled by RANKL, reducing bone resorption in in-vitro assays”.
Adalta managing-director Dr Tim Oldham said the work “further demonstrates the potential of the i-body platform to engage diverse targets to modify disease”.
“We look forward to continuing to support Prof Xu and his team as they work to discover improved therapies for osteoporosis,” Dr Oldham said.
“We have applied for a patent to protect this invention and are open to industry collaborations to advance this program,” Dr Oldham said.
Adalta was up 0.8 cents or 21.05 percent to 4.6 cents.

RECCE PHARMACEUTICALS

Recce says it has received $4,311,202 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Recce said the rebate related to research and development expenditure for the year to June 30, 2022.
The company said it had borrowed $1,908,039 from Radium Capital against its expected research and development tax incentive, at a 1.25 percent compound rate per month.
Recce was up two cents or 3.1 percent to 67 cents.

CRESO PHARMA

Creso has requested a trading halt “pending an announcement regarding a debt restructuring transaction” and a potential acquisition.
Trading will resume on January 30, 2023 or on an earlier announcement.
Creso last traded at 2.2 cents.

VOLPARA HEALTH TECHNOLOGIES

Harbour Asset Management says it has increased its holding in Volpara from 33,056,183 shares (13.115%) to 35,593,522 shares (14.118%).
The New Zealand-based fund said that between October 18, 2022 and January 24, 2023 it bought 2,537,339 shares for $1,631,622, or an average of 64.3 cents a share.
Volpara was up 2.5 cents or three percent to 85 cents.

ADALTA

Meurs Group says it has increased its substantial holding in Adalta from 17,856,001 shares (5.68%) to 53,594,168 shares (17.06%).
The Melbourne-based Meurs Group said that through Skiptan Pty Ltd and Meurs Holdings Pty Ltd, it bought shares between November 20, 2020 and February 7, 2022 with the single largest purchase 4,109,589 shares for $300,000, or 7.3 cents a share.
The company said that through YCLP Pty Ltd it also acquired 27,029,924 shares "in-specie" on January 23, 2023.
Yesterday, Yuuwa Capital said it transferred its 54,059,848 Adalta shares off-market to two undisclosed substantial shareholders associated with the fund (BD: Jan 24, 2023).
Adalta said at that time the transfer of shares was part of Yuuwa Capital's end-of-fund wind-up.
The substantial shareholder notice said that Peter Meurs was the sole director of YCLP and Skiptan, and one of the directors of Meurs Holdings.

COGSTATE

Cogstate says David Dolby has resigned as a non-executive director, effective from today.
According to ASX data, Mr Dolby was appointed a director on November 24, 2013.
In 2013, the Dagmar Dolby Trust said it had become a substantial shareholder with 8,108,108 shares (8.04%) bought at 37.0 cents a share (BD: Nov 26, 2013).
In 2019, Dagmar Dolby said it held 21,391,389 Cogstate shares or 15.06 percent of the company (BD: July 10, 2019).
Mr Dolby said "as a part of my family's estate planning, we are planning to gift substantially all of our Cogstate shares to the Dagmar Dolby Fund, a California based charitable foundation".
Cogstate was unchanged at $2.00.