



# Biotech Daily

Thursday February 16, 2023

*Daily news on ASX-listed biotechnology companies*

- \* **ASX UP, BIOTECH EVEN: COMPUMEDICS UP 14%; NOVA EYE DOWN 15%**
- \* **INVENTIA TO USE MERCK'S RASTRUM FOR NEURO SCREENING**
- \* **WOKE, CURTIN UNI SIGN PSILOCYBIN WP002 PAIN TRIAL DEAL**
- \* **NUHEARA SHIPS 1<sup>st</sup> HP PRO SELF-FIT HEARING AIDS TO US**
- \* **CLARITY CU-64-SARTATE NEURO-ENDOCRINE TRIAL '50% RECRUITED'**
- \* **ALTERITY: FRANCE, AUSTRIA APPROVE ATH434 MSA PHASE II TRIAL**
- \* **NEUROTECH TREATS 1<sup>st</sup> PATIENT IN NTI164 MARIJUANA PSYCH TRIAL**
- \* **MASON STEVENS BELOW 5% IN PATRYS**
- \* **CARL CHARALAMBOUS BELOW 5% IN EXOPHARM**

## MARKET REPORT

The Australian stock market was up 0.79 percent on Thursday February 16, 2023, with the ASX200 up 58.1 points to 7,410.3 points.

Sixteen of the Biotech Daily Top 40 stocks were up, 15 fell and nine traded unchanged.

Compumedics was the best, up 2.5 cents or 13.9 percent to 20.5 cents, with 60,000 shares traded. Avita climbed 5.3 percent; Antisense, Atomo and Kazia improved four percent or more; Immutep, Imugene, Mesoblast and Nanosonics were up more than three percent; Opthea, Polynovo and Telix rose more than two percent; Cynata and Starpharma were up more than one percent; with Cochlear, Medical Developments, Proteomics and Resmed up by less than one percent.

Nova Eye led the falls, down four cents or 14.8 percent to 23 cents, with 70,534 shares traded. Uscom lost 11.1 percent; Dimerix fell 7.7 percent; Cyclopharm was down 6.75 percent; Amplia shed 5.6 percent; Genetic Signatures and Next Science fell more than four percent; Pro Medicus lost 3.4 percent; Emvision shed two percent; Actinogen, Paradigm, Universal Biosensors and Volpara were down one percent or more; with Clinuvel, CSL and Neuren down by less than one percent.

## INVENTIA LIFE SCIENCE

Inventia says it will use Merck Sharp & Dohme's Rastrum three-dimension (3-D) cell culture platform for pre-clinical screening of neurodegenerative disease treatments. The Sydney-based Inventia said that the Rastrum 3-D cell culture platform was designed to "enable the generation of highly reproducible cell models that closely mimic the human brain".

The company said that the physiological complexity of the cell cultures could allow laboratory-based research and discovery.

Inventia said that the collaboration with the Kenilworth, New Jersey-based Merck Inc (Merck Sharp & Dohme outside the US), use the Rastrum bio-printing capabilities "to create 3-D in-vitro models for the pre-clinical screening of neuro-degenerative disease therapeutic candidates".

Inventia chief executive officer Dr Julio Ribeiro said the company was "committed to working with MSD to establish better in-vitro models for neurodegenerative diseases". "We aim to establish new approaches to drug discovery and create more translatable models which bridge the gap between in-vitro and in-vivo preclinical studies," Dr Ribeiro said.

Merck Sharp & Dohme biology executive director Dr Jill Richardson said the collaboration "leverages MSD's deep expertise in neuroscience and drug discovery with Inventia's novel 3-D bio-printing platform to develop more relevant and translational models of the brain with the aim of enhancing pre-clinical screening for neurodegenerative disease candidates".

Inventia is a private company.

## WOKE PHARMACEUTICALS

Woke says it has a formal trial agreement with Curtin University for a 50-patient, phase II trial of psilocybin with psychotherapy for chronic primary musculo-skeletal pain.

In December 2022, Woke said Curtin University would run a 50-patient, phase II trial of 25mg synthetic psilocybin WP002 with psychotherapy for chronic primary musculo-skeletal pain (BD: Dec 20, 2022).

At that time, the company said Curtin University psychologist Dr Rob Schütze would conduct the trial, which would examine the safety, tolerability and proof-of-concept efficacy.

Today, Woke said that the randomized, controlled trial would collaborate with Melbourne's Monash University, the University of Western Australia and the George Institute in Sydney to examine the safety, tolerability and efficacy of WP002 in patients suffering from chronic pain.

Woke chief executive officer Nick Woolf said "WP002 psilocybin therapy with relevant psychotherapy could offer benefit to these patients, who have limited treatment options, by addressing the psychological component of chronic pain as well as potentially targeting pain pathways".

Dr Schütze said that "initial findings from observational studies suggest that psychedelics can benefit people with chronic pain".

"The mode of action is likely to be through accelerating psychological and behavioral changes, while potentially having direct effects on pain neurophysiology," Dr Schütze said.

"This trial aims to explore the effect of Woke's WP002 psilocybin in a randomized controlled trial with targeted pain psychotherapy," Dr Schütze said.

Woke is a private company.

## [NUHEARA](#)

Nuheara says it expects to ship the first batch of its self-fitting Hewlett-Packard Hearing Pro hearing aids to the US “prior to the end of this month”.

In 2022, Nuheara said that the Sacramento, California-based Innerscope Hearing Technologies would market and sell its over-the-counter, self-fit hearing aids in the US (BD: Dec 12, 2022).

Last year, Nuheara said the US Food and Drug Administration had approved the self-fitting, over-the-counter Hewlett-Packard Hearing Pro hearing aid under the 510(k) pathway (BD: Oct 31, 2022).

Today, the company said it had completed all pre-production manufacturing runs for its hearing aid as well as the mass production phase.

Nuheara managing-director Justin Miller said that “having built a strong back-order book of sales, we are looking forward to seeing our hearing aids on US retail shelves”.

“With [over-the-counter] hearing aids a new substantial retail category in the US covering 38 million people, retailers and other healthcare providers in that market responded very positively to our launch of the HP Hearing Pro last month,” Mr Miller said.

Nuheara was up two cents or 10.3 percent to 21.5 cents.

## [CLARITY PHARMACEUTICALS](#)

Clarity says it has recruited more than half of its 63-patient, phase II trial of its copper-64-Sartate imaging agent for neuro-endocrine tumors.

Clarity said the ‘Diagnostic Imaging Study of 64-Copper-Sartate Using PET on Patients With Known or Suspected Neuroendocrine Tumors’ was known as the ‘Disco’ trial.

In 2021, Clarity said it had dosed the first participant in the trial, which used positron emission tomography (PET) on patients with known or suspected gastro-entero-pancreatic neuro-endocrine tumors, to assess the potential of Cu-64 Sartate to diagnose those tumors (BD: Apr 15, 2021).

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

Clarity fell one cent or 1.2 percent to 82 cents.

## [ALTERITY THERAPEUTICS](#)

Alterity says it has regulatory approval from France and Austria for its 60-patient, phase II randomized, double-blind, controlled trial of ATH434 for multiple system atrophy (MSA).

In 2022, Alterity said the US Food and Drug Administration had approved its application for ATH434 for early-stage multiple system atrophy and it had begun the trial in Sydney, exploring the efficacy of two doses ATH434 as well as characterization of safety and pharmacokinetics (BD: Sep 20, Oct 13, 2022).

Today, the company said the trial would include wearable sensors to evaluate motor activities that are important to patients with multiple system atrophy.

Alterity chief executive officer Dr David Stamler said “the regulatory approvals in France and Austria will allow us to expand our footprint in Europe and are another important step forward for our ATH434 development program”.

“With the trial now open in five countries we are focused on providing access to our phase II clinical trial for individuals living with MSA,” Dr Stamler said. “We expect to open trial sites in France and Austria over the next few months.”

Alterity was up 0.05 cents or 5.9 percent to 0.9 cents with 7.3 million shares traded.

## NEUROTECH INTERNATIONAL

Neurotech says the first of 15 patients has been treated in the phase I/II trial of the marijuana-based NTI164 for children with neuro-psychiatric disorders.

In January, Neurotech said it had ethics approval for a multi-site, open-label trial studying the safety and efficacy of its low delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD) combination drug, NTI164, in children with paediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (Pandas) and paediatric acute-onset neuropsychiatric syndrome (Pans) (BD: Jan 27, 2023).

At that time, the company said that the primary endpoints were the revised children's anxiety and depression scale, the clinical global impression-severity and improvement, and that secondary endpoints included the Yale global tic severity scale, as well as other clinical scales.

Today, Neurotech said that it expected recruitment to be completed by April 2023, with results expected by the end of 2023.

The company said that the trial was open for enrolment at Sydney's Children's Hospital at Westmead and the Paediatric Neurology Unit at Melbourne's Monash Medical Centre.

Neurotech executive director Dr Thomas Duthy said the company believed NTI164 had "the potential to reduce the neuro-inflammation associated with Pandas/Pans, which is postulated to play a role in the pathogenesis in the majority of cases."

"Neuro-inflammation is one of the main triggers for neuro-degeneration," Dr Duthy said.

Neurotech fell 0.2 cents or 3.6 percent to 5.3 cents.

## PATRYS

Mason Stevens says it has reduced its holding in Patrys from 111,000,699 shares (5.40%) to 102,813,020 shares (4.99%).

The Sydney-based Mason Stevens said that it bought and sold shares between February 3, and February 14, 2023, with the single largest sale of 11,073 shares for \$354 or 3.2 cents a share.

Patrys was unchanged at 2.8 cents.

## EXOPHARM

Brisbane's Carl Charalambous says he has ceased his holding in Exopharm after selling 9,902,254 shares for \$168,447 or 1.7 cents a share on February 13, 2023.

In 2022, Mr Charalambous said he increased his substantial holding in Exopharm from 15,468,243 shares (9.84%) to 17,216,270 shares (10.95%) (BD: Oct 24, 2022).

Exopharm was unchanged at 1.5 cents with 1.96 million shares traded.