# Biotech Daily

Monday May 10, 2021

*Daily news on ASX-listed biotechnology companies*

*** ASX UP, BIOTECH DOWN: OPTISCAN UP 10%; ACTINOGEN DOWN 5%**

*** AUDEARA $7m IPO FOR SPECIALIST HEADPHONES**

*** TGA OKAYS TELIX PROSTACT TLX591-CDX PROSTATE CANCER TRIAL**

*** ADHERIUM REJECTS RESPIRI OFFER**

*** OVENTUS PLACEMENT TO RAISE $5m, 1-FOR-4.4 RIGHTS FOR $5m**

*** PRESCIENT, PETER MAC RESEARCH OMNICAR FOR CANCERS**

*** NUHEARA SHIPS 1st HEWLETT PACKARD ELITE EARBUDS**

*** BIONOMICS ADDS SOCIAL ANXIETY DISORDER TO BNC210 TRIALS**

*** RACE: BISANTRENE COMBINATIONS FOR AML, IN-VITRO**

*** OSTEOPORE: PRODUCT VARIANTS CE MARK; SHELF-LIFE EXTENDED**

*** TDM TAKES 25% OF SOMNOMED**

*** CLIME REDUCES TO 8% IN MACH7**

*** PETERS INVESTMENTS TAKES 11.4% OF OPTISCAN**

*** PHILLIP (BIOSCIENCE MANAGERS) TAKES 23.5% OF ADHERIUM**

*** VIBURNUM TAKES 11% OF ADHERIUM**

*** FIL (FIDELITY) TAKES 10% OF ADHERIUM**

## MARKET REPORT

The Australian stock market was up 1.3 percent on Monday May 10, 2021, with the ASX200 up 92.0 points to 7,172.8 points. Fourteen of the Biotech Daily Top 40 stocks were up, 16 fell and 10 traded unchanged. All three Big Caps were up.

Optiscan was the best, up four cents or 10.3 percent to 43 cents, with 1.9 million shares traded. Neuren climbed 8.9 percent; Cyclopharm, Immutep and Mesoblast improved five percent or more; Impedimed and Telix were up more than four percent; Cynata was up 3.4 percent; Orthocell rose 2.8 percent; Kazia, LBT, Resmed and Starpharma were up more than one percent; with Clinuvel, Cochlear, CSL and Nanosonics up less than one percent.

Actinogen led the falls, down 0.3 cents or 5.3 percent to 5.4 cents, with nine million shares traded. Genetic Signatures and Patrys fell four percent or more; Alterity, Universal Biosensors and Volpara were down more than three percent; Amplia, Nova Eye and Prescient shed two percent or more; Next Science, Pharmaxis, Polynovo and Pro Medicus were down more than one percent; with Avita, Medical Developments and Paradigm down by less than one percent.

## AUDEARA

Brisbane's Audeara says its initial public offer for $7 million at 20 cents a share has closed and it expects to list on the ASX on Friday May 14, under the code AUA.

An Audeara spokesperson told Biotech Daily that the company had developed and was selling "full-fidelity headphones with a built-in hearing test".

In its prospectus Audeara said it was incorporated on February 23, 2015, by Brisbane doctors and engineers, Dr James Fielding, Dr Chris Jeffery and Alex Afflick.

The company said its products were manufactured through a third-party in Shenzhen, China, and it generated $965,0000 in revenue for the year to December 31, 2020.

In a letter to investors in the prospectus, Audeara chair David Trimboli said the company was "a hearing health technology company that has developed a hearing profile algorithm used to personalize sound output to the needs of the individual".

"The first product to be designed, commercialized and produced is the Audeara A–01 headphone with accompanying BT–01 Bluetooth transceiver," Mr Trimboli said.

"Our platform allows customers with hearing deficits to enjoy sound personalized for their unique hearing profile, offering a superior sound experience and quality," Mr Trimboli said.

Mr Trimboli said the company was registered with the Federal Government Operated Hearing Services Program, the National Disability Insurance Scheme and the Department of Veterans' Affairs Rehabilitation Appliances Program.

Audeara said it currently had 70,000,000 shares on issue and the $7 million raising would value the company at $21,000,000.

The company said its board comprised chair Mr Trimboli, Dr Fielding as managing-director and Pasquale Rombola a non-executive director, with Mr Afflick its chief technical officer, Jason Thorogood the chief operating officer and Peter Harding-Smith the chief financial officer and company secretary.

The prospectus is available at: https://audearaoffer.thereachagency.com/offer/.

## TELIX PHARMACEUTICALS

Telix says the Australian Therapeutic Goods Administration has approved its 390-patient, phase III of TLX591-CDx for advanced metastatic prostate cancer.

Telix said the Prostact, multi-centre, randomized controlled trial would enrol patients with prostate-specific membrane antigen (PSMA)-expressing advanced metastatic castrate-resistant prostate cancer, following prior treatment with a novel androgen axis drug.

The company said it would use its 68-gallium-PSMA-11 imaging to select patients and compare standard-of-care alone against standard-of-care with TLX591-CDx.

Telix said that the primary endpoint was radiographic progression-free survival, with secondary endpoints including overall survival and assessment of quality of life.

Telix chief executive officer Dr Christian Behrenbruch told Biotech Daily it was the company's "priority to get patients into the trial as quickly as possible".

In a media release to the ASX Dr Behrenbruch said the start of the trial marked "a major corporate milestone for Telix that brings the company a step closer to delivering on a major unmet medical need for treatment options in this patient population".

"TLX591 has demonstrated promising and competitive clinical potential that we believe warrants further confirmation in this second-line disease setting," Dr Behrenbruch said.

"It is also noteworthy that Telix's differentiated approach to integrating molecular imaging with [positron emission tomography] alongside therapy, enables a comparatively streamlined study that we believe will support efficient patient enrolment and study execution," Dr Behrenbruch said.

Telix was up 19 cents or 4.8 percent to $4.13 with 449,738 shares traded.

ADHERIUM, RESPIRI

Adherium says it rejects Respiri's “unsolicited off-market takeover offer” having reviewed the offer and discussed it with major shareholders.

In April, Respiri offered to exchange one Respiri share for seven Adherium shares valuing Adherium at 2.25 cents a share or $19.14 million, and saying the exchange rate was a 50.2 percent premium to Adherium’s closing share price of 1.5 cents at the close of trade on April 28 (BD: Apr 30, 2021).

In March, Adherium said it had raised $18 million in placement at 1.5 cents led by Trudell Medical and Bioscience Managers (BD: Mar 18, 2021).

Today, Adherium said that, in the absence of a superior offer, the board unanimously recommended it “be rejected by shareholders by taking no action in relation to the offer”.

The company said it would make a full response in a target's statement to be circulated after Respiri's bidder's statement.

Adherium said that rather than “derisk” an investment in Adherium the takeover “would increase risk” as investors would be subject to the risk profile of both companies”.

The company said that there was a “weak strategic alignment” and Respiri’s commercial strategy through pharmacies and direct-to-consumer was unsuccessful for Adherium previously and Respiri’s strategy was “yet to be proven”.

“Respiri has only one sensor, for which … there are no publicly available independent clinical trial results, and nor is it supported by any independently-conducted clinical trial publications in peer reviewed journals,” Adherium said.

The company said the clinical significance of measuring wheeze in the treatment of asthma and chronic obstructive pulmonary disease (COPD) and whether this would qualify for reimbursement, in particular in the US, had not been independently demonstrated or verified.

Adherium said its Hailie system with internet cloud and mobile application software had six regulatory cleared sensors with eight US Food and Drug Administration clearances for inhaled medication covering more than 56 percent of the market by unit sales volume in the US, with additional clearances for Canada, China and Europe.

The company said “the scope of its development plan and its commercialization for the Hailie platform is substantially greater than that of Respiri's Wheezo product”.

Under the headline of ‘Opportunistic and conditional nature of the Respiri offer’ Adherium said the offer was not cash, but shares subject to a range of risks including regulatory risks, such as the failure to have a method for measuring "wheeze" recognized as qualifying for US reimbursement and commercialization risks including the failure to launch Wheezo in its initial market, Australia, noting the market price of Wheezo had reduced significantly since launch and based on Respiri's Appendix 4C lodged on April 29, 2021, Respiri had not gained traction in its direct-to-consumer and pharmacy model as cash receipts from customers in the March 31, 2021 quarter were $1,000, with cash receipts in the nine months to March 31, 2021 were $174,000, compared with Respiri's revenue guidance to the market of $6 million to $8 million in the 2021 calendar year.

The company said the Respiri offer was “highly opportunistic given Adherium, following conversion of the Viburnum secured convertible notes and completion of the capital raise has no debt and has just raised $18 million.

Adherium noted that different timepoints showed different rates of share price premium and on the date the offer was announced Respiri’s share price was 12.5 cents and Adherium’s was 1.6 cents implying a premium of 11.6 percent “and there is no guarantee at what price Respiri shares may trade in the future”.

Adherium was unchanged at 1.7 cents with 6.7 million shares traded.

Respiri fell 0.9 cents or 8.6 percent to 9.6 cents with 4.8 million shares traded.

## OVENTUS MEDICAL

Oventus says it has “firm commitments” to raise $5 million in a placement at 12 cents a share and expects to raise a further $5 million in an underwritten one-for-4.4 rights offer.
Oventus said that investors in the placement and rights offer would receive one attaching option for every two new shares acquired, exercisable at 24 cents within two years.
The company said that directors would invest a minimum of $200,000, pending shareholder approval.
Oventus said the funds would be used to strengthen its balance sheet, enhance its manufacturing operations, logistics, sales, marketing activities, and support restructuring and costs related to the reduction in operating costs.
The company said that the offer price was a 30.6 percent discount to the 5-day volume-weighted average price to May 5, 2021.
Oventus said the record date for the entitlement offer was May 18, the offer would open on May 21 and close on June 7, 2021.
The company said the placement was co-led by Canaccord Genuity Australia and Bell Potter Securities, and the two companies had fully underwritten the rights offer.
Oventus fell three cents or 18.2 percent to 13.5 cents.

## PRESCIENT THERAPEUTICS

Prescient says it will work with Melbourne’s Peter MacCallum Cancer Centre to develop its Omnicar platform for three different types of cancer.
Last year, Prescient said it had licenced an immune receptor platform from the University of Pennsylvania and a related molecular binding system Oxford University. to develop a chimeric antigen receptor (CAR) cell therapy platform named Omnicar, and would work with the Peter MacCallum Centre to develop cell therapy technologies, including chimeric antigen receptor T-cell (CAR-T) therapies (BD: May 26, Aug 18, 2020).
Today, the company said the collaboration would be led by Prof Phil Darcy and would investigate Omnicar for acute myeloid leukemia, human epidermal growth factor receptor 2 positive (Her2+) solid tumors, and glioblastoma multiforme.
The company said it had received $100,000 from the Federal Government’s Innovation Connections scheme for the research.
In January, the company said Omnicar was “a universal immune receptor technology platform that offers a number of potential benefits over existing Car-T therapies, including control, safety, flexibility and efficacy” (BD: Jan 18, 2021).
Today, Prescient said that Omnicar would seek to overcome the limitations of the current CAR-T approaches by providing clinicians with greater control, safety, flexibility, efficacy and the “potential to improve CAR-T performance against solid tumors”.
Prescient fell 0.2 cents or 2.25 percent to 8.7 cents with 6.1 million shares traded.

## NUHEARA

Nuheara says it has shipped its first batch of Elite wireless earbuds under the three-year supply agreement to Hewlett-Packard Inc.
Last month, Nuheara said it had begun manufacturing its Elite wireless earbuds to be an option bundled with Hewlett-Packard notebook computers (BD: Apr 21, 2021).
Nuheara fell 0.1 cents or 2.2 percent to 4.4 cents with 5.7 million shares traded.

## BIONOMICS

Bionomics says it will evaluate BNC210 for social anxiety disorder as well as continue planning its phase IIb trial for post-traumatic stress disorder in June.

In 2018, Bionomics fell 69 percent when its 193-patient, phase II trial of anti-anxiety drug BNC210 in adults with post-traumatic stress disorder (PTSD), failed to meet its primary endpoint (BD: Oct 2, 2018).

In February, Bionomics said that seven-day dosing of a new oral formulation of BNC210, at 900mg twice daily, showed steady-state 12-hourly exposure (BD: Feb 22, 2021).

Today, the company said BNC210's "successful" phase IIa study in generalized anxiety disorder patients showed acute administration of the liquid suspension formulation of BNC210 had "significant anti-anxiety effects as measured in brain imaging and behavioral studies" and was similar to benzodiazepines like lorazepam but without "evidence for sedation or addictive potential".

In 2016, Bionomics said the 24-patient, phase II trial of BNC210 for generalized anxiety met its primary endpoints of change in cerebral perfusion and task-related brain activity, with the secondary endpoint of suppressing anxiety-related defensive behavior measured by the 'joystick-operated runway task' out-performing lorazepam (BD: Sep 21, 2016).

In 2015, the company said that the phase II trial would compare BNC210 300mg or 2000mg, placebo and 1.5mg lorazepam, while the Monthly Index of Medical Supplies and the UK Medicines & Healthcare Products Regulatory Agency said the maximum dose of lorazepam was up to 4mg a day (BD: Apr 20, 2015)

Today, Bionomics said the phase IIb PTSD trial would compare 900mg BNC210 twice daily against placebo for the improvement of PTSD.

The company said the trial would be conducted at Morrisville, North Carolina-based Premier Research and in partnership with Dr Frank Weathers.

Bionomics fell one cent or 4.2 percent to 23 cents with 1.1 million shares traded.

## RACE ONCOLOGY

Race says that a number of clinically translatable drug combinations show synergy with Bisantrene for acute myeloid leukaemia, in-vitro.

Race said it funded the researche, led by the chair of its advisory committee Prof Borje Andersson and the Houston-based MD Anderson Cancer Center's Prof Ben Valdez, who had "identified a number of clinically translatable drug combinations that showed synergy with Bisantrene when tested in acute myeloid leukaemia cells".

The company said the research paper, titled 'Synergism of the Anthracene-Derivative Anti-Cancer Agent Bisantrene with Nucleoside Analogs and A Bcl-2 Inhibitor in Acute Myeloid Leukemia Cells' was published in the Journal of Clinical and Experimental Oncology, with the full article available at: https://bit.ly/2RIYd6Q.

Race said Bisantrene in combination with the standard-of-care acute myeloid leukaemia drugs cytarabine, cladribine, fludarabine, clofarabine and/or ABT199 (Ventoclax) "showed enhanced activation of apoptosis" or cell killing in acute myeloid leukaemia cells.

The company said that combinations of three or more of these drugs with Bisantrene "showed additional synergism and effective cell killing at drug concentrations far below that observed when the drugs were used on their own".

Race chief scientific officer Dr Daniel Tillett said the pre-clinical data supported the planned phase II trial for relapsed or refractory acute myeloid leukaemia at Tel Aviv's Chaim Sheba Medical Center, where patients would be treated with Bisantrene combined with the nucleoside analogs, clofarabine and fludarabine, due to begin by July 2021.

Race was up 17 cents or 5.2 percent to $3.44 with 634,595 shares traded.

## OSTEOPORE

Osteopore says the Conformité Européenne (CE) mark has been extended for its wound treatment products and shelf-life increased from two years to three years.
Osteopore said the CE mark has been granted to its products Osteomesh, Osteoplug, Osteoplug-C sizes and seven shape variants.
Osteopore chief executive officer Goh Khoon Seng said the products “work with the body’s natural regenerative capabilities rather than having to rely on artificial replacement parts”.
“This expanded approval means more patients have access to the benefits of [the] technology when undergoing cranial surgery,” Mr Goh said.
Osteopore was up one cent or two percent to 50.5 cents.

## SOMNOMED

TDM Growth Partners says it has increased its substantial shareholding in Somnomed from 20,700,384 shares (25.01%) to 20,837,628 shares (25.18%).
The Sydney-based TDM Growth Partners said it bought 137,244 shares for $2.07 a share.
TDM said the shares were held directly, by TDMAM Pty Ltd, Madleowill Investments and Zoolander Investments.
Somnomed was up four cents or 1.9 percent to $2.19.

## MACH7 TECHNOLOGIES

Clime Investment Management says it has decreased its substantial shareholding in Mach7 from 19,810,832 shares (9.11%) to 19,047,502 shares (8.08%).
The Sydney-based Clime and its subsidiaries said that between June 19, 2020 and May 5, 2021 it bought and sold shares at prices ranging from 66 cents to $1.55 a share.
Mach7 fell five cents or 4.4 percent to $1.095 with 1.1 million shares traded.

## OPTISCAN IMAGING

Peters Investments says it has increased its substantial shareholding in Optiscan from 43,431,112 shares (10.32%) to 70,000,000 (11.37%).
The Cottesloe, Western Australia-based Peters Investment said it bought 26,568,888 shares on-market, in a placement and share plan for $4,985,047 or an average of 18.8 cents a share.
Last year Optiscan said it had raised $9,813,499 in a placement at 8.25 cents a share (BD: Sep 22, 2020.
Optiscan was up four cents or 10.3 percent to 43 cents with 1.9 million shares traded.

## ADHERIUM

Phillip Asset Management says it has increased its substantial shareholding in Adherium from 166,666,667 shares (19.62%) to 500,000,000 shares (23.52%).
Phillip Asset Management said it was acting as trustee for Bioscience Managers Translation Fund 1.
In March, Adherium said it had “subscription commitments” to raise $18 million in a placement at 1.5 cents a share including $5 million each from Trudell Medical and Bioscience Managers Translation Fund 1 (BD: Mar 18, 2021).

ADHERIUM

Viburnum says it has become a substantial shareholder in Adherium with 238,989,991 shares or 11.24 percent of the company.

Perth's Viburnum said it acquired the shares through the conversion of a secured convertible note including principal and interest.

Last year, Adherium said it had a $3m convertible note with Viburnum, with an interest rate of 9.0 percent per annum and converting at 3.0 cents a share (BD: Oct 26, 2020).

ADHERIUM

The Hong Kong-based FIL says it has increased its substantial shareholding in Adherium from 44,681,769 shares (7.43%) to 211,645,356 shares (9.96%).

FIL said it acquired the shares in a placement at 1.5 cents a share (see above).