

ABN 53 075 582 740

# **BIONOMICS LIMITED**

ASX Results Announcement, Directors' Report and Financial Statements – 30 June 2021

Lodged with the ASX under Listing Rule 4.3A

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#### **BIONOMICS LIMTED**

Year ended 30 June 2021

(previous corresponding period: year ended 30 June 2020)

Results for Announcement to the Market \$					
	Cash and cash equivalents as at 30 June 2021 from 30 June 2020	increased by	523%	to	28,499,449
	<b>Net operating and investing cash outflows</b> for the period	increased by	86%	to	7,618,930
	Revenue from continuing operations	decreased by	100%	to	NIL
)	Other income from continuing operations	decreased by	61%	to	1,308,343
	Other gains and losses from continuing operations	decreased by	7%	to	4,272,931
	Loss from continuing operations after tax	increased by	49%	to	8,697,037
	Loss from discounted operations	decreased by	100%	to	NIL
	Loss for the year	decreased by	22%	to	8,697,037
NTA Backing					
	Net tangible asset backing per ordinary share	<b>2021</b> \$2.86	<b>20</b> (\$0.76)		

# Explanation of cash and cash equivalents position as at 30 June 2021:

The closing cash and cash equivalents position is in line with expectations and reflects net proceeds from share issues offset by repayments of borrowing and net cash used in operating activities (principally relating to research and development activities).

# Explanation of net movement in operating and investing cash outflows:

The net movement includes ongoing core R&D expenditure on the Company's clinical programs BNC210 and the continued development of the product pipeline.

#### Explanation of revenue from continuing operations:

In the current period there was no revenue, prior period revenue (\$46,662) related to licence fees received.

#### Explanation of other income from continuing operations

Other income predominately consists of the Australian R&D Tax incentive and has decreased as a result of reduced eligible research and development expenditure.

#### Explanation of loss from continuing operations after tax:

The increase in current year loss from continuing operations principally reflects the reduction in other income, and other gains and losses and increase in expenses (administration expenses offset by reduction in finance expenses).

#### **Explanation of loss from discontinued operations**

The loss from discontinued operation only relates to the year ended 30 June 2020, as on 3 March 2020, the Company sold its two wholly owned French subsidiaries, Neurofit SAS and PC SAS, which carry out all the Group's contract service business resulting in a loss on disposal of \$1,299,313.

# Explanation of loss for the year

The increase in current year loss principally reflects the reduction in other income, and other gains and losses and a net increase in expenses (increase in administration expenses offset by reduction in finance expenses) offset by effect of the loss on disposals the Company's two French subsidiaries that occurred during the year end 30 June 2020 as there was no discounted operations for the year end 30 June 2021.

#### Dividends/Distributions

Bionomics Limited does not propose to pay any dividend for the year ended 30 June 2021.



ASX ANNOUNCEMENT 25 August 2021

# BIONOMICS REPORTS FULL YEAR FINANCIAL RESULTS

Bionomics Limited (ASX:BNO, OTCQB:BNOEF), today announced its financial results for the 12 months ended 30 June 2021.

Bionomics is a clinical stage biopharmaceutical company developing novel, allosteric ion channel modulators designed to transform the lives of patients suffering from serious central nervous system disorders with high, unmet medical needs. Bionomics is advancing its lead product candidate, BNC210, an oral, proprietary selective Negative Allosteric Modulator of the  $\alpha$ 7 nicotinic acetylcholine receptor (" $\alpha$ 7 receptor") for the acute treatment of Social Anxiety Disorder ("SAD") and chronic treatment of Post-Traumatic Stress Disorder ("PTSD").

During the year ended 30 June 2021, Bionomics announced that as part of its broader pipeline expansion strategy and based on anti-anxiety efficacy signals in Generalised Anxiety Disorder patients, it would proceed with evaluating BNC210 as an acute treatment in SAD. Additionally, Bionomics advanced BNC210 in PTSD with the start of its Phase 2b ATTUNE study in July 2021. The ATTUNE study is a randomised, placebo-controlled study to evaluate the effects of twice daily dosing (900 mg) of the Company's newly developed tablet formulation of BNC210. This BNC210 dosing regimen was demonstrated in a 7-day pharmacokinetic study in healthy subjects to exceed the 12-hourly blood exposure of ~25 mg.h/L predicted as necessary to meet the primary endpoints for effectiveness for treating PTSD patients in future clinical trials. The top line data from the BNC210 Phase 2b ATTUNE study are projected for the first half of 2023.

The Company's expertise and approach have been validated through its strategic partnership with MSD (known as Merck in the United States and Canada) for the Positive Allosteric Modulator program, which targets the  $\alpha 7$  receptor that has garnered significant attention for treating cognitive deficits. The MSD collaboration currently includes two candidates that are in early-stage Phase 1 safety and biomarker clinical trials for treating cognitive impairment. The first compound has completed Phase 1 safety clinical trials in healthy subjects and there are ongoing plans for further biomarker studies. In 2020, a second molecule that showed an improved potency profile in preclinical animal models was advanced by Merck under this collaboration into Phase 1 clinical trials.

#### Additional Key Highlights:

- Completed the raising of approximately \$44 million in gross proceeds from the issuance of new shares through various share placements and rights offerings with approximately 380 million new shares being issued in aggregate.
- Successfully repaid the remainder of its approximately \$6.2 million external borrowings outstanding at 30 April 2021 resulting in the termination of all commitments and obligations under the loan agreements.

- Continued activities to maximise the value of legacy oncology programs through licensing in November 2020 of BNC101 to Carina Biotech for CAR-T therapy development and recent completion of the Australasian Gastro-Intestinal Trials Group-sponsored Phase 2 BNC105/nivolumab combination trial for the treatment of metastatic colorectal cancer.
- The cash position at 30 June 2021 was \$28,499,449 with restricted cash of \$554,640 classified as other financial assets (2020: restricted cash of \$436,174).

#### **Future Outlook**

Bionomics expects to initiate activities in Q3 CY2021 to finalise the trial design, engage a clinical research organisation and submit the requisite regulatory filings necessary for initiation of BNC210 acute treatment of SAD; the timings related to start and completion of the trial will be disclosed in this time period.

Bionomics announced its plans to conduct a registered initial public offering of American Depositary Shares ("ADSs") in the United States and a concurrent listing of ADSs on Nasdaq. The number of ADSs and price of the proposed offering have not yet been determined. The proposed offering is expected to commence after the U.S. Securities and Exchange Commission completes its review process of a registration statement relating to the proposed offering ("the Registration Statement") that the company intends to file, and subject to market and other conditions, including the effectiveness of the Registration Statement and shareholder approval under Australian Securities Exchange ("ASX") Listing Rule 7.1. Each ADS would represent a certain number of fully paid ordinary shares in Bionomics. No final decision has been made in respect of the Nasdaq listing and there can be no assurance as to the occurrence, timing or completion of such a listing. Following any Nasdaq listing Bionomics shares would continue to trade on ASX.

Bionomics advised that it is expecting to propose, in connection with and prior to any such U.S. public offering, to make a capital distribution representing an economic interest in the net after tax royalty payments (if any), received by the Company under its exclusive Research Collaboration and License Agreement with MSD relating to BNC375 and related compounds. This capital distribution will be distributed as a financial asset, on a per share basis, to shareholders holding Bionomics shares on a record date to be set prior to the proposed U.S. public offering. The precise form of the financial asset is yet to be determined. The Company expects that the distribution, should it take place, would be implemented by an equal capital reduction and a scheme of arrangement, requiring shareholder and court approvals. Bionomics will advise further information concerning the distribution in due course. There is no certainty that the distribution will take place.

AUTHORISED BY THE BOARD.
FOR FURTHER INFORMATION PLEASE CONTACT:

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#### **About Bionomics Limited**

Bionomics (ASX: BNO, OTCQB: BNOEF) is a clinical-stage biopharmaceutical company leveraging its proprietary platform technologies to discover and develop a deep pipeline of best-in-class, novel drug candidates for patients affected by central nervous system (CNS) disorders. Bionomics' lead drug candidate BNC210 is a negative allosteric modulator of the α7 nicotinic acetylcholine receptor. BNC210 oral tablet formulation is currently being evaluated in a second Phase 2b trial for the treatment of Post-Traumatic Stress Disorder (PTSD) for which it was granted Fast Track designation by the FDA. BNC210 is also being evaluated as an acute treatment in Social Anxiety Disorder (SAD) patients and is expected to enter a Phase 2 trial. In addition, Bionomics has entered into a Memorandum of Understanding with EmpathBio Inc, a wholly owned subsidiary of Germany-based CNS clinical development company, atai Life Sciences, to collectively explore a combination drug treatment regimen with Bionomics' BNC210 and EmpathBio's 3,4-

Methylenedioxymethamphetamine (MDMA) derivative EMP-01 for the treatment of PTSD. Beyond BNC210, Bionomics has a strategic partnership with Merck & Co., Inc (known as MSD outside the United States and Canada) with two drugs in early-stage clinical trials for the treatment of cognitive deficits in Alzheimer's disease. www.bionomics.com.au

#### **Factors Affecting Future Performance**

This announcement contains "forward-looking" statements within the meaning of the United States' Private Securities Litigation Reform Act of 1995. Any statements contained in this announcement that relate to prospective events or developments, including, without limitation, statements made regarding Bionomics' drug candidates (including BNC210, BNC101 and BNC105), its licensing agreements with Merck & Co. and any milestone or royalty payments thereunder, drug discovery programs, ongoing and future clinical trials, and timing of the receipt of clinical data for our drug candidates are deemed to be forward-looking statements.

Words such as "believes," "anticipates," "plans," "expects," "projects," "forecasts," "will" and similar expressions are intended to identify forward-looking statements. There are a number of important factors that could cause actual results or events to differ materially from those indicated by these forward-looking statements, including unexpected safety or efficacy data, unexpected side effects observed in clinical trials, risks related to our available funds or existing funding arrangements, our failure to introduce new drug candidates or platform technologies or obtain regulatory approvals in a timely manner or at all, regulatory changes, inability to protect our intellectual property, risks related to our international operations, our inability to integrate acquired businesses and technologies into our existing business and to our competitive advantage, as well as other factors. Results of studies performed on our drug candidates and competitors' drugs and drug candidates may vary from those reported when tested in different settings.