ABN 53 075 582 740

# BIONOMICS LIMITED

## ASX Results Announcement, Directors' Report and Financial Statements – 30 June 2019

Lodged with the ASX under Listing Rule 4.3A

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**BIONOMICS LIMTED**
Year ended 30 June 2019
(previous corresponding period: year ended 30 June 2018)

**Results for Announcement to the Market**

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|---|---|---|---|---|
| **Cash and cash equivalents as at 30 June 2019** from 30 June 2018 | decreased by | 43.9% | to | 13,985,477 |
| **Net operating and investing cash outflows** for the period | decreased by | 24.5% | to | 15,384,252 |
| **Revenue** from ordinary activities | increased by | 1.9% | to | 4,029,059 |
| **Revenue and other income** | decreased by | 6.5% | to | 11,642,006 |
| **Loss** from ordinary activities after tax attributable to members | decreased by | 61.5% | to | 9,669,115 |

**NTA Backing**

| | **2019** | **2018** |
|---|---|---|
| Net tangible asset backing per ordinary share | 3.2 cents | 6.9 cents |

**Explanation of cash and cash equivalents position as at 30 June 2019:**
The closing cash and cash equivalents position is in line with expectations and reflects the Company's investment in research and development.

**Explanation of net movement in operating and investing cash outflows:**
The net movement includes the completion of core R&D expenditure on the Company's clinical programs BNC210 and the continued development of the product pipeline.

**Explanation of revenue from ordinary activities:**
Revenue consists of contract service revenue of Bionomics' wholly-owned subsidiaries Neurofit and Prestwick, rental and interest income received as a result of ordinary activities and other income including the government's R&D Tax Incentive in Australia and similar incentives for the subsidiaries.

**Explanation of net profit from ordinary activities after tax:**
The reduced current year loss reflects the Company's reduction in investment in research and development activities following completion of the BNC210 Post Traumatic Stress Disorder (PTSD) and Agitation trials.

**Dividends/Distributions**
Bionomics Limited does not propose to pay any dividend for the year ended 30 June 2019.

Bionomics Limited

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**ASX ANNOUNCEMENT**
**20 August 2019**

# BIONOMICS REPORTS FULL YEAR FINANCIAL RESULTS

**Adelaide, Australia**: Bionomics Limited (ASX:BNO, OTCQX:BNOEF), today announced its financial results for the 12 months to 30 June 2019.

## Clinical Development and Operational Highlights

- In October 2018, we announced the results of the Phase 2 clinical trial of BNC210 in patients with Post Traumatic Stress Disorder (PTSD) in 193 patients with PTSD across 25 sites in the US and Australia (referred to as the "RESTORE" trial). The primary endpoint of this study was a decrease in PTSD symptoms between placebo and BNC210 treatment groups as measured by the Clinician-Administered PTSD Scale (CAPS-5) at 12 weeks. The CAPS-5 is a standardised structured clinical interview and serves as the standard in clinical development and regulatory approval for measuring the symptom severity of PTSD. Earlier versions of the CAPS were used to support the approval of the two currently marketed PTSD treatments. We found that BNC210 showed excellent tolerability and safety but the primary endpoint was not met.

- In November 2018, we announced leadership changes with Dr Errol De Souza, becoming Executive Chairman of Bionomics from 12 November 2018 and Dr Deborah Rathjen retiring as Managing Director on 9 November 2018 and as Chief Executive Officer of Bionomics on 31 January 2019. In addition we announced the commencement of a strategic review of the options for the Company led by Greenhill & Co. Dr De Souza's appointment was extended in March and June 2019 to 30 June 2019 and 20 November 2019, respectively.

- Also in November 2018, BVF Partners L.P. led a recapitalisation of the Company with a private placement (and top up right) raising $9,849,787 and increasing their holding in Bionomics from approximately 10.02% to approximately 19.9% of issued capital. Under the terms of the placement, BVF were entitled to nominate a director to the Board of Bionomics and their nominee was Mr Mitchell Kaye. Bionomics institutional shareholders and retail investors were given an opportunity to participate in the raise.

- In February 2019, we announced that additional data analysis conducted in Sweden by Pharmetheus AB showed a statistically significant response when drug exposure versus response was measured in the Phase 2 PTSD RESTORE Trial. The exposure-response analysis uses patient blood levels of the drug, regardless of the administered dose, to relate estimates of drug exposure to the response measured in the trial patients. The analysis demonstrated reduction in total PTSD symptoms as measured by total CAPS-5, the endpoint mandated by the US Food & Drug Administration (FDA) for PTSD trials.

- The Company determined to seek FDA guidance on the next steps for BNC210 for PTSD including the design of a further trial and whether BNC210 is eligible for Fast Track designation

whilst also identifying an improved solid dose formulation of BNC210 with potential to overcome the “food effect” and the consequent variable blood levels that were evident in the PTSD trial where the patients were administered BNC210 in a liquid suspension formulation.

- In December 2018, the Company received A$6,568,808 R&D Tax Incentive Refund for the 2017/2018 financial year, and a further A$1,324,459.29 was received in July 2019 plus interest of $17,593.18, following an internal review of our application by the Department of Industry, Innovation & Science. The Company also received A$654,000 in licensing revenue from its successful participation in the Cancer Therapeutics CRC (CTx). The CTx has licensed two targets to Pfizer Inc under a potential US$460M deal.

- In January 2019, we announced an experimental Phase 2 clinical trial of our cancer drug candidate, BNC105, in combination with Bristol-Myers Squibb’s nivolumab had commenced in patients with metastatic colorectal cancer, in an Australasian Gastro-Intestinal Trials Group (AGITG) sponsored trial supported by Bristol-Myers Squibb. The trial continues recruitment of a total of ~40 patients with a targeted completion in 2020.

- In May 2019, we announced the formal completion and results of the independent strategic review conducted with the assistance of Greenhill & Co., Inc. The Company continues to evaluate out-licensing opportunities and potential merger candidates but no assurance can be given that these efforts will lead to a proposal the Board can recommend to shareholders. In the meantime, we continue to focus on advancing the pipeline, assessing the strategic options for partnering and portfolio prioritisation while cutting our costs to extend our cash runway.

- In May 2019, we announced the publication of a paper describing the generation of the novel class of compounds which led to the discovery on BNC375 in the scientific journal, ACS Medicinal Chemistry Letters. Bionomics’ BNC375 research program initiated the exclusive Research Collaboration and License Agreement between Bionomics and Merck & Co., Inc., Kenilworth, NJ USA (known as MSD outside the United States and Canada). MSD continues to conduct clinical development to evaluate the asset.

- In June 2019, we announced the topline results of the exploratory trial of BNC210 for the treatment of agitation in elderly patients in a hospital setting which indicated that BNC210 treatment did not differentiate from placebo on the primary and secondary endpoints. The safety of BNC210 was confirmed, but we will not be pursuing this indication.

- In June 2019, we announced our decision to invest in a single ascending dose study in healthy volunteers to demonstrate that blood levels of BNC210 believed to be necessary to meet the primary endpoints for effectiveness for treating PTSD in any further trial are achievable using the new solid dose formulation. The results are anticipated to be available by early 4Q CY2019.

**Key Points – Financial**

- Cash at 30 June 2019 was $13,985,477, a decrease of $10,944,984 over the 30 June 2018 balance.
- Revenue and other income for the period was $11,642,006 compared with $12,456,446 for the period to 30 June 2018.
- The operating loss after tax of the Group for the period was $9,669,115 compared to $25,085,564 for the previous fiscal year.

- Net operating and investments cash outflow decreased to $15,384,252 from $20,371,547 for the previous fiscal year reflecting completion of the Phase 2 clinical trial of BNC210 in PTSD, the completion of the exploratory Phase 2 clinical trial of BNC210 in Agitation and the continued development of the product pipeline with preclinical programs targeting pain and cognition.
- Bionomics continues to focus on cost efficiency in supporting activities, conserving cash for research and development.

## Outlook

Bionomics continues to progress its development of BNC210 in PTSD and to focus on its important relationship with MSD. Anticipated forthcoming milestones include:

- Bionomics solid dose formulation pharmacokinetic study results are expected early CY4Q 2019.
- Bionomics expects feedback from its Type C meeting with the FDA in early CY4Q 2019.
- Whilst the internal focus and current R&D spend is restricted to CNS programs, Bionomics continues activities to maximise the value of its legacy oncology programs through externally funded clinical development, divestment and/or out-licensing both BNC101 and BNC105.
- Bionomics continues to focus on conserving cash to extend its cash runway.

**FOR FURTHER INFORMATION PLEASE CONTACT:**

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**About Bionomics Limited**
Bionomics (ASX: BNO) is a global, clinical stage biopharmaceutical company leveraging its proprietary platform technologies to discover and develop a deep pipeline of best in class, novel drug candidates. Bionomics' lead drug candidate BNC210, currently in Phase 2 for the treatment of agitation, is a novel, proprietary negative allosteric modulator of the alpha-7 (α7) nicotinic acetylcholine receptor. Beyond BNC210, Bionomics has a strategic partnership with Merck & Co., Inc (known as MSD outside the United States and Canada).
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.