Bionomics

CREATING INNOVATIVE THERAPIES
FOR CNS DISORDERS.

# INVESTOR PRESENTATION – PRO RATA ENTITLEMENT OFFER

**Thursday, 24 September 2020**
**BNO (Australia: ASX); BNOEF (USA: OTCQB)**

NOT FOR DISTRIBUTION OR RELEASE IN THE UNITED STATES

Central Nervous System (CNS)

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The Equity Raising will be made to:

- Eligible institutional shareholders of Bionomics (**Institutional Entitlement Offer**) and
- Eligible retail shareholders of Bionomics (**Retail Entitlement Offer**).

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# Overview

- Bionomics is undertaking a 1 for 12.54 accelerated non-renounceable pro rata entitlement offer of new fully paid ordinary shares in Bionomics (**New Shares**) at an offer price of $0.04 per New Share
- The Equity Raising comprises an accelerated institutional entitlement offer (**Institutional Entitlement Offer**) and a retail entitlement offer (**Retail Entitlement Offer**)
- The Retail Entitlement Offer will include an oversubscription facility that allows eligible retail shareholders who accept their entitlement in full to apply for additional New Shares equal in number to up to a maximum of 100% of their entitlement (available to the extent New Shares are not taken up by other eligible shareholders)
- Funds raised under the Equity Raising will be used to partly fund development activities up to and including a second Phase 2 trial by Bionomics in Post-Traumatic Stress Disorder

# Bionomics Investment Highlights

- Global, clinical stage biopharmaceutical company developing a pipeline of novel drug candidates targeting ion channels in Central Nervous System (CNS) disorders
- Lead clinical candidate BNC210 in Phase 2 with Fast Track designation from FDA for Post-Traumatic Stress Disorder (PTSD)
- Strategic partnership with Merck & Co., with multiple therapeutic candidates for cognitive impairment in development for Alzheimer's Disease
- Emerging CNS partnering pipeline of ion channel candidates for treatment of pain and cognitive deficits
- Additional value in non-core Phase 1-2 oncology assets through external funding and partnering
- Experienced Management and Board of Directors
- Strong international investor base
- Financials: Market Capitalisation (as at 16 September., 2020) of ~ A$100 M;
- Cash at 30 June 2020: ~A$4.58 M; ~A$17.2 M in committed or underwritten funding (FIRB approval granted)

# BNC210: Next Generation Drug Candidate with Potential to Treat Anxiety, Depression, PTSD and other Stress-Related Disorders

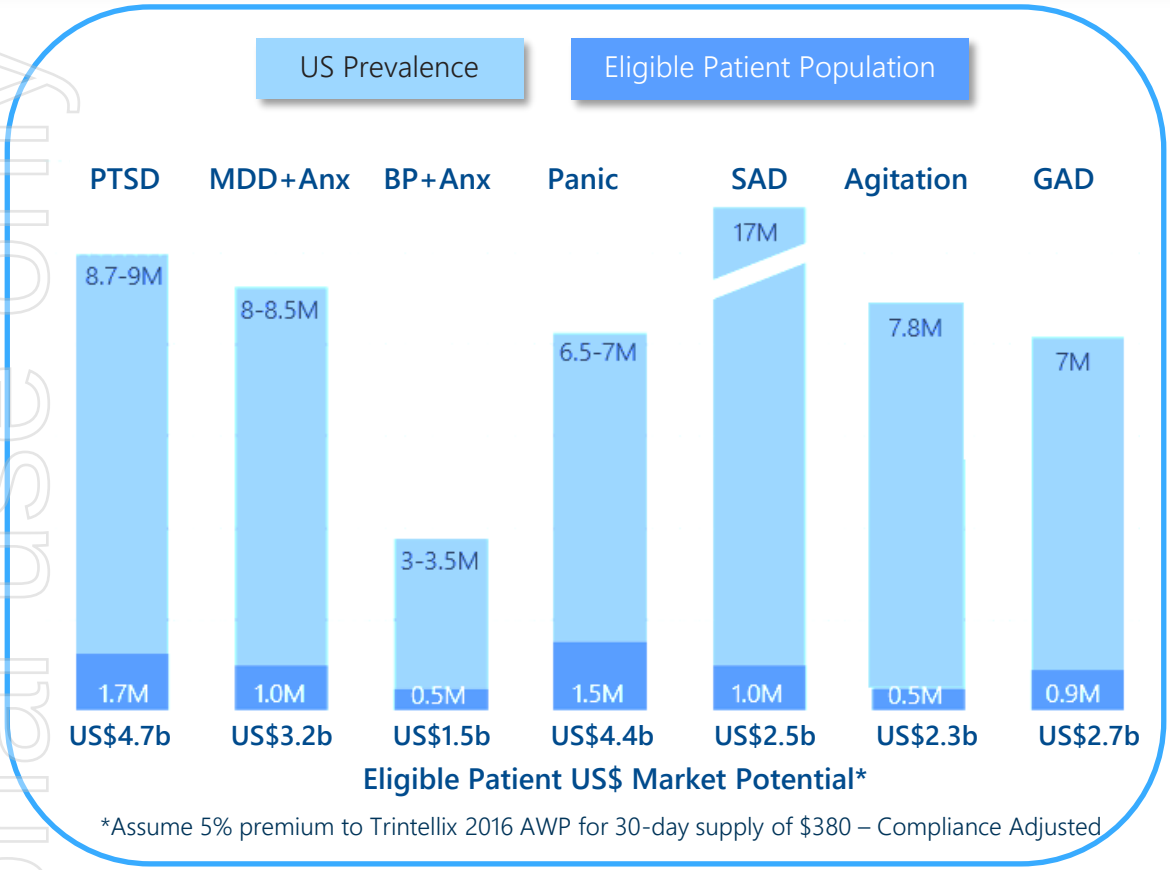
- Novel, orally-administered, first-in-class, negative allosteric modulator (NAM) of the α7 nicotinic acetylcholine receptor
- Large market potential for treatment of multiple psychiatric indications
- Strong safety database in man – 11 trials with exposure in ~400 subjects
- Demonstrated nicotinic receptor target engagement in healthy subjects
- Proof of biology in healthy subjects (anti-panic) and in Generalized Anxiety Disorder patients (anti-anxiety)

## Potential Competitive Advantages of BNC210*

| Drug | No sedation | No withdrawal syndrome | No memory impairment | Fast acting | No drug/drug interactions |
|---|---|---|---|---|---|
| BNC210 | ✓ | ✓ | ✓ | ✓ | ✓ |
| Valium and other benzodiazepines | X | X | X | ✓ | ✓ |
| Prozac and certain other SSRIs/SNRIs | ✓ | X | ✓ | X | X |

*Based on data from preclinical studies, Phase 1 & 2 clinical trials.

# BNC210 Targets Multi-Billion Dollar Markets with Unmet Need: US Market Potential




*Assume 5% premium to Trintellix 2016 AWP for 30-day supply of $380 – Compliance Adjusted

- ✓ Innovative, first-in-class
- ✓ Unmet need in large patient population
- ✓ Advancement in care
- ✓ Limited branded competition
- ✓ Ability to achieve large market share

[1] 3.4-4% prevalence >18yrs., ~25% of patients diagnosed and treated
[2] 6.7% prevalence, ~50% co-morbid anxiety, ~50% diagnosed and treated
[3] ~2.9% prevalence, 50% co-morbid anxiety (range in literature 25 to 75%), ~50% diagnosed and treated
[4] ~2.7% prevalence, ~50% diagnosed and treated
[5] ~6.8% prevalence, 15-20% diagnosed and treated
[6] ~3.1% dementia prevalence >40yrs., ~9% agitation patients diagnosed and treated
[7] 3.1% GAD prevalence, assumes ~25% diagnosed and treated, ~50% of SSRI patients treated are partial responders or relapsers

Post-Traumatic Stress Disorder (PTSD) Major Depressive Disorder (MDD) Bipolar Disorder (BP) Social Anxiety Disorder (SAD) Generalized Anxiety Disorder (GAD)







Bionomics

# Phase 2 Trial of BNC210 in Adults with Generalized Anxiety Disorder (GAD)

- 24 GAD participants administered single doses of BNC210, lorazepam and placebo were exposed to "fearful faces" while in a Magnetic Resonance Imaging (MRI) machine or performing a behavioural task
- BNC210 demonstrated acute anxiolytic (anti-anxiety) activity by significantly:
  - Reducing activation in the amygdala caused by viewing "fearful faces"
  - Reducing connectivity between the amygdala and anterior cingulate cortex which is very strong in high anxiety
  - Reducing threat avoidance behaviour in the anxious participants
- BNC210 was safe and well tolerated in patients with GAD

# First Phase 2 Trial of BNC210 in Adults with PTSD

## 2018

- Results of the first trial of 193 PTSD participants administered BNC210 or placebo over a 12 week period showed no overall effect of BNC210 on PTSD symptom severity as measured by CAPS-5 (Clinician-Administered PTSD Scale for DSM-5) scores
- BNC210 was safe and well tolerated in patients with PTSD
- Results indicated that the liquid suspension formulation of BNC210 did not achieve the exposure in the out-patient setting for BNC210 to be effective due to compliance and to the requirement to be taken with food

# Bionomics has Achieved Key Milestones Towards Continuing Development of BNC210 for the Treatment of PTSD

## 2019

- ✓ Pharmacometric analysis of the first Phase 2 PTSD trial data showed that there is potential for significant patient benefit in future trials provided adequate drug exposure is achieved
- ✓ Successful development of a BNC210 solid dose tablet formulation not required to be taken with food. Evaluation of solid dose formulation in single dose PK studies achieved exposures adequate for future development
- ✓ FDA Type C Meeting provided positive feedback on the BNC210 development program for the treatment of PTSD
- ✓ FDA granted Fast Track designation to BNC210 for the treatment of PTSD

# BNC210 is Back on Track to Leverage Large Opportunity for Treatment of PTSD

## 2020: Preparations for Phase 2b PTSD Trial

- Optimised and selected the tablet formulation for a Phase 2b clinical trial
- Manufacturing underway of BNC210 tablets for a multiple dosing PK trial in healthy volunteers scheduled for late Dec 2020/Jan 2021
- Large scale manufacture of BNC210 drug substance and tablets for Phase 2b trial have been contracted

## 2021 – 2022: Implementation of Phase 2b PTSD Trial

- Conduct a Phase 2b clinical trial in ~200 PTSD patients comparing one dose of BNC210 with placebo on the change in CAPS-5 total severity scores at 12 weeks – target start date of late 2QCY2021
- CAPS-5 is the FDA-accepted primary endpoint for PTSD clinical trials

# Global License and Collaboration Agreement with MSD (Merck & Co.) in Cognition Provides Validation

Partnership generated US$20M in upfront payment in 2014, research funding 2014-2017 and reached its US$10M first clinical milestone in February 2017. Deal valued up to US$506M in upfront, research and milestone payments plus additional royalties on net sales of licensed drugs.

MSD (a tradename of Merck & Co., Inc., Kenilworth NJ USA)Collaboration Update:

- Phase 1 safety clinical trials of the lead molecule in healthy subjects have been completed and there are ongoing plans for further biomarker studies
- A backup molecule that showed an improved potency profile in preclinical animal models versus the current lead molecule is advancing into Phase 1 clinical trials


- Agreement covers research on BNC375 and related compounds
- BNC375 demonstrated potent memory enhancing properties in animal models – both episodic and working memory improved
- Targeting cognitive impairment in Alzheimer's, Parkinson's and other conditions

# Emerging CNS Pipeline for Partnering

- Small molecule Kv3.1 / Kv3.2 potassium ion channels activators
  - Kv3.1 / Kv3.2 activators represent a promising therapeutic strategy for improving cognitive dysfunction and negative symptoms in schizophrenia and other illnesses such as Autism Spectrum Disorder and Alzheimer's Disease
  - ~600 compounds synthesized; 3 chemical series developed and 2 series patented
  - Lead compound BL-76 fully reverses PCP-induced cognitive deficit in mice in the T-maze test
- Small molecule pan Nav inhibitors for treatment of chronic pain
  - Gain and loss-of-function mutations in Nav1.7, 1.8 and 1.9 have been associated with human pain
  - 1000+ compounds synthesized; 3 chemical series developed and patented
  - Bionomics' pan Nav inhibitors with functional selectivity for voltage gated sodium channels Nav1.7, Nav1.8 and potentially Nav1.9 offer potential to develop non-addictive therapeutics for chronic pain with less side effects

# Value in Non-Core Phase 1-2 Oncology Assets Leveraged Through External Funding and Partnering

- BNC105 - a Multi-Modal Small Molecule Tubulin Polymerization Inhibitor has completed four Phase 1 and Phase 2 clinical trials
  - Two externally-funded investigator-initiated clinical trials are in progress:
    - Phase 2 trial of BNC105 in combination with nivolumab (Opdivo) for the treatment of metastatic colorectal cancer sponsored by the Australasian Gastro-Intestinal Trials Group (AGITG) and funded by BMS; patient enrolment at 16 sites across Australia is complete with final results projected for early 2023
    - Phase 1 trial of BNC105 in combination with ibrutinib (Imbruvica) for the treatment of chronic lymphocytic leukemia funded by the Leukemia & Lymphoma Society (US)
- BNC101 - a First-in-Class Humanized Monoclonal Antibody to LGR5, a Cancer Stem Cell Receptor
  - BNC101 clinical dose and schedule were established in a Phase 1 trial in patients with metastatic colorectal cancer (CRC) - the recommended Phase 2 dose was identified
  - Phase 2 ready: BNC101 in combination with standard of care treatment for gastro-intestinal cancers overexpressing LGR5
  - Potential for BNC101 to be developed as an Antibody-Drug-Conjugate (ADC) therapeutic or in combination with CAR-T being explored

# Bionomics Outlook

- **Balanced business model with potential for short term milestones to drive shareholder value:**
  - Internal development of BNC210 is back on track with a solid dose formulation to achieve the blood exposure required for future PTSD trials, along with positive feedback from the FDA and Fast Track designation provide a promising opportunity for the company in 2020 and beyond
  - Strengthened strategic investor base with committed or underwritten funding for BNC210 development (FIRB approval granted)
  - We continue to pursue licensing and partnering possibilities for our core CNS pain and cognition programs and have an ongoing collaboration with Merck & Co.
  - Maximise the value and partnering potential of legacy oncology assets through external funding of clinical programs
  - Cost cutting measures implemented in 2019 along with leveraging Australian R&D Tax Incentive Refund allow us to extend cash runway with non-dilutive funding

# Equity Raising Overview

| | |
|---|---|
| Offer structure and size | A 1 for 12.54 accelerated non-renounceable pro rata entitlement offer (**Equity Raising**), comprising:<br>• an accelerated institutional entitlement offer (**Institutional Entitlement Offer**); and<br>• a retail entitlement offer (**Retail Entitlement Offer**). |
| Pricing | An offer price of $0.04 per New Share, which represents:<br>• 76.5%. discount to the TERP* of Wednesday, 23 September 2020; and<br>• 77.8% discount to the closing price of fully paid ordinary shares in Bionomics (**Shares**) on Wednesday, 23 September 2020, being $0.18. |
| Institutional Entitlement Offer | • The Institutional Entitlement Offer will be conducted by way of a bookbuild process, which will open on Thursday, 24 September 2020 and close on Friday 25 September 2020. |
| Retail Entitlement Offer | • The Retail Entitlement Offer will open on Thursday, 1 October 2020 and close at 5.00pm (Adelaide time) on Thursday, 15 October 2020.<br>• The Retail Entitlement Offer is open to all eligible shareholders with a registered address in Australia or New Zealand who were not invited to participate in the Institutional Entitlement Offer and are not in the United States or acting for the account or benefit of a person in the United States. |
| Ranking | • The New Shares issued under the Equity Raising will be fully paid and rank equally with existing Bionomics Shares on issue. |
| Record Date | • 6.30pm (Adelaide time) on Monday, 28 September 2020. |

*The Theoretical Ex-Rights Price (**TERP**) is the theoretical price at which Bionomics shares should trade after the ex-date for the Equity Raising. TERP is a theoretical calculation only and the actual price at which Bionomics shares trade immediately after the ex-date of the Equity Raising will depend on many factors and may not be equal to TERP. TERP is calculated by adjusting for the bonus-element of the Equity Raising based on the closing price of Bionomics shares on Wednesday, 23 September 2020.

# Sources and uses*

| Sources | Amount | Uses |
|---|---|---|
| Gross proceeds from Institutional Entitlement Offer | $893,235 | Part funding of development activities up to and including a second Phase 2 trial by Bionomics in Post-Traumatic Stress Disorder. |
| Gross proceeds from Retail Entitlement Offer | $1,280,085 | Part funding development activities up to and including a second Phase 2 trial by Bionomics in Post-Traumatic Stress Disorder. |
| **Total sources of funds** | **$2,173,320** | |

*Before costs associated with the Equity Raising and assuming the Equity Raising is fully subscribed.

# Pro forma balance sheet

| | Actual 1 July 2020 $ | Second Placement Issue * $ | Equity Raising (100% take-up) $ | Costs $ | Pro forma 1 July 2020 $ |
|---|---|---|---|---|---|
| **Current Assets** | | | | | |
| Cash and cash equivalents | 4,577,747 | 2,173,320 | 2,173,320 | (50,000) | 8,874,387 |
| Other Current Assets | 3,755,151 | - | - | - | 3,755,151 |
| Total Current Assets | 8,332,898 | 2,173,320 | 2,173,320 | (50,000) | 12,629,538 |
| Total Non-Current Assets | 26,129,958 | - | - | - | $26,129,958 |
| Total Assets | 34,462,856 | 2,173,320 | 2,173,320 | (50,000) | 38,759,496 |
| Total Current Liabilities | 8,272,106 | - | - | - | 8,272,106 |
| Total Non-Current Liabilities | 13,508,743 | - | - | - | 13,508,743 |
| Total Liabilities | 21,780,849 | - | - | - | 21,780,849 |
| Net Assets | 12,682,007 | $2,173,320 | 2,173,320 | (50,000) | 16,978,647 |
| **Total Equity** | **12,682,007** | **2,173,320** | **$2,173,320** | **(50,000)** | **16,978,647** |

* Second placement of shares issued to Apeiron Investments Group Ltd and others on 21 September 2020, as approved by shareholders at the EGM held on 26 August 2020

# Equity Raising timetable

| | |
|---|---|
| Announcement of the Equity Raising | Thursday, 24 September 2020 |
| Institutional Entitlement Offer opens | Thursday, 24 September 2020 |
| Institutional Entitlement Offer closes | Friday, 25 September 2020 |
| Trading resumes. Shares recommence trading on an "ex-entitlement" basis | Monday, 28 September 2020 |
| Record Date for the Retail Entitlement Offer | 6.30pm (Adelaide time) Monday, 28 September 2020 |
| Retail Offer booklet dispatched; Retail Entitlement Offer opens | Thursday, 1 October 2020 |
| Settlement of shares issued under the Institutional Entitlement Offer | Monday, 5 October 2020 |
| Commencement of trading of shares issued under the Institutional Entitlement Offer | Tuesday, 6 October 2020 |
| Retail Entitlement Offer closes (unless extended) (**Retail Closing Date**) | 5.00pm (Adelaide time) Thursday, 15 October 2020 |
| Issue of New Shares under the Retail Entitlement Offer | Thursday, 22 October 2020 |
| New shares issued under the Retail Entitlement Offer commence trading on ASX | Friday, 23 October 2020 |

# Appendix A

## Key Risks

# Key risks – Company specific

This section discusses some of the key risks associated with an investment in Bionomics. Bionomics' business is subject to a number of risk factors both specific to its business and of a general nature which may impact on its future performance and forecasts. Before subscribing for Bionomics shares, prospective investors should carefully consider and evaluate Bionomics and its business and whether the shares are suitable to acquire having regard to their own investment objectives and financial circumstances and taking into consideration the material risk factors set out below. The risk factors set out below are not exhaustive. Prospective investors should consider publicly available information on Bionomics, examine the full content of this presentation and consult with their financial or other advisers before making an investment decision.

| | |
|---|---|
| Incurred significant losses to date and anticipate incurring significant losses in the foreseeable future | Bionomics is a clinical-stage biopharmaceutical company and the Board expects Bionomics to continue to incur losses for the foreseeable future. The Board anticipates that the rate at which Bionomics incurs losses will increase as it continues its development of, seeks regulatory approval for and, if approved, begins commercialisation of BNC210 for the treatment of Post Traumatic Stress Disorder (PTSD). If BNC210 fails in clinical trials or does not gain regulatory approval, or if any of Bionomics' drug candidates, if approved, fail to achieve market acceptance or adequate market share, Bionomics may never generate revenue or become profitable. |
| Failure of Bionomics to raise capital | Bionomics' capital requirements will depend on numerous factors. Research and development costs and pursuit of its business plan will reduce Bionomics' cash reserves, which may not be replaced through future operations, should these prove unsuccessful or perform below expectations. Bionomics would in such cases be dependent on seeking additional capital elsewhere, whether through equity, debt or joint venture financing. Failure to raise may raise a "going concern" issue.<br><br>Bionomics is likely to require further financing and to undertake future capital raisings. There is a risk that Bionomics may fail to raise sufficient capital to develop and implement its business plan in the future. General instability and uncertainty in the global economic environment means that equity funding may be difficult to obtain and the Directors may form the view that any fundraising activities should be deferred. |

# Key risks – company specific (cont.)

| | |
|---|---|
| Failure of Bionomics to raise capital (cont.) | The Board can give no assurance as to the levels of future borrowings or further capital raisings that will be required to meet the aims of Bionomics. No assurance can be given that Bionomics will be able to procure sufficient funding at the relevant times on terms acceptable to it.<br><br>Any additional future equity financing will dilute the shareholdings of existing shareholders of Bionomics (**Shareholders**) and any debt financing, if available, may involve restrictions on Bionomics' operating activities and business strategy. If Bionomics is unable to obtain additional funding as needed, it may be required to reduce the scope of its operations or scale back its business plans or research and development plans, as the case may be which could have a material adverse effect on Bionomics' activities. |
| Research and development success | Bionomics' drug candidates and compounds in its discovery, preclinical and clinical pipeline are in varying stages of development and will require substantial clinical development, testing and regulatory approval prior to commercialisation. It may be several more years before these drug candidates receive regulatory approval, if ever. If any of Bionomics' drug candidates fail to become approved drugs, its business, financial condition, results of operations and prospects may be adversely affected and the trading price of Bionomics' securities may decline.<br><br>The commercialisation of Bionomics' "off strategy" preclinical and clinical oncology assets is dependent on out-licensing activities which may or not be successful. If successful, out-licensing revenue will be milestone driven payments and/or royalties if the drug candidate reaches the necessary sales revenue thresholds.<br><br>Bionomics' collaboration with Merck & Co (known as **MSD** outside the US and Canada) to develop drug candidates targeting cognitive dysfunction associated with Alzheimer's disease and other CNS conditions is dependent on MSD completing all preclinical and clinical development and obtaining and maintaining regulatory approval for the applicable drug candidates from the US Food & Drug Administration (**FDA**). If such drug candidates are advanced through clinical trials and receive regulatory approval from the FDA, MSD will be responsible for commercialisation. Thus the potential for Bionomics to obtain future development milestone payments and, ultimately, generate revenue from royalties on sales of such collaboration drugs depends entirely on successful development, regulatory approval, marketing and commercialisation by its collaboration partner. |

# Key risks – company specific (cont.)

| | |
|---|---|
| Operations | Bionomics is highly dependent on the principal members of its senior management and scientific staff, the loss of whose services could adversely affect the achievement of its development objectives. Bionomics could also experience difficulty attracting and retaining such employees in the future. Competition for qualified personnel in the biotechnology and pharmaceuticals fields is intense due to the limited number of individuals who possess the skills and experience required by the industry. As such, Bionomics could have difficulty attracting experienced personnel and may be required to expend significant financial resources in its employee recruitment and retention efforts.<br><br>Bionomics also relies on third parties, such as contract laboratories, Contract Research Organisations (CROs), Contract Manufacturing Organisation (CMOs), medical institutions, academic institutions and clinical investigators to conduct its manufacturing, preclinical studies and clinical trials. While Bionomics will have agreements governing these third parties' activities, Bionomics only controls certain aspects of their activities and has limited influence over their actual performance. The third parties with whom Bionomics contracts for manufacturing and execution of preclinical studies and clinical trials play a significant role in the conduct of these studies and trials and the subsequent collection and analysis of data. Although Bionomics relies on these third parties to conduct its manufacturing, preclinical and clinical trials, it remains responsible for ensuring that each of its manufacturing activities, preclinical studies and clinical trials are conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and Bionomics' reliance on third parties does not relieve it of these responsibilities.<br><br>Bionomics' internal computer systems and those of its third-party CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorised access, natural disasters, terrorism, war and telecommunication and electrical failures. While Bionomics has not experienced any such system failure, accident or security breach to date, if such an event were to occur, it could result in a material disruption of Bionomics' programs. |

# Key risks – company specific (cont.)

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| Operations (cont.) | The COVID-19 pandemic has not affected Bionomics' preclinical or clinical operations to date, but the Board cannot rule out that it may impact Bionomics' operations in the future. The timely completion of clinical trials in accordance with their protocols depends, among other things, on Bionomics' ability to enrol a sufficient number of suitable patients who remain in the study until its conclusion. If Bionomics experiences delays, as a result of the pandemic or otherwise, in completing its clinical trials, such delays could result in increased costs, delays in advancing its drug development, delays in testing the effectiveness of its drug candidates or termination of the clinical trials altogether. |
| Insurance risks | Bionomics insures its operations in accordance with industry practice. However, in certain circumstances, Bionomics' insurance may not be of a nature or level to provide adequate insurance cover. The occurrence of an event that is not covered or fully covered by insurance could have a material adverse effect on the business, financial condition and results of Bionomics. Insurance against all risks associated with research and development and clinical trials may not always be available and where available the costs can be prohibitive. |
| Reliance on key personnel | Bionomics' business relies on a number of key executives and officers. If any of the key executives or officers leave Bionomics, this may have an adverse effect on its operations, financial position and/or performance. |

# Key risks – industry specific

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| Regulatory approval risk | The research, testing, manufacturing, labelling, approval, selling, import, export, marketing and distribution of drug and biological products are subject to extensive regulation by the FDA and comparable regulatory authorities in other jurisdictions, which regulations differ from country to country. Neither Bionomics nor any of its collaboration partners is permitted to market any drugs or biological products until Bionomics receives regulatory approval from the FDA. Marketing authorisation can be a lengthy, expensive and uncertain process.<br><br>The number of nonclinical studies and clinical trials that will be required for approval by the FDA and comparable authorities, and the time required to obtain approval, typically takes many years following the commencement of clinical trials and depends upon numerous factors. The FDA and comparable authorities have substantial discretion in the approval process and Bionomics may encounter matters with the FDA, or comparable authorities that requires it to expend additional time and resources and delay or prevent the approval of its drug candidates. Despite the time and expense exerted, failure can occur at any stage.<br><br>This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in Bionomics' failure to obtain regulatory approval to market any of its drug candidates, which would significantly harm its business, financial condition, results of operations and prospects.<br><br>In addition, even if Bionomics obtains approval, regulatory authorities may approve any of its drug candidates for fewer or more limited indications than it requests, may not approve the price it intends to charge for its drugs, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a drug candidate with a label that does not include the labelling claims necessary or desirable for the successful commercialisation of any future drug. Any of the foregoing scenarios could harm the commercial prospects for Bionomics' drugs. |

# Key risks – industry specific (cont.)

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| Safety and efficacy risks | Clinical trials often fail to demonstrate safety and efficacy of the drug candidate studied for the target indication. Most drug candidates that commence clinical trials are never approved as drugs. If Bionomics' drug candidates are not shown to be both safe and effective in clinical trials, it will not be able to obtain regulatory approval or commercialise these drug candidates. In such case, Bionomics would need to develop other compounds and conduct associated preclinical studies and clinical trials, as well as consider the potential need for additional financing, which would have a material adverse effect on its business, financial condition, results of operations and prospects. |
| Manufacturing or formulation risks | As drug candidates are developed through to late stage clinical trials towards approval and commercialisation, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimise processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause Bionomics' drug candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of drug candidates or jeopardise Bionomics' or its collaborators' ability to commence drug sales and generate revenue. |
| Risks in obtaining regulatory approvals across jurisdictions | Sales of Bionomics' approved drugs will be subject to U.S. regulatory requirements governing clinical trials and regulatory approval, and Bionomics plans to seek regulatory approval to commercialise its drug candidates in the United States and other countries. Clinical trials conducted in the United States may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. |

# Key risks – industry specific (cont.)

**Unexpected drug side effects and related risks**

Undesirable side effects caused by Bionomics' drug candidates could cause Bionomics or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable regulatory authority. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential drug liability claims. In addition, these side effects may not be appropriately recognised or managed by the treating medical staff. Bionomics expects to have to train and/or inform medical personnel using its drug candidates to understand the side effect profiles for its clinical trials and upon any commercialisation of any of its drug candidates. Inadequate training or information in recognizing or managing the potential side effects of Bionomics' drug candidates could result in patient injury or death. Any of these occurrences may harm Bionomics' business, financial condition and prospects significantly.

If any of Bionomics' drug candidates receive marketing approval, and Bionomics or others later identify undesirable side effects caused by such drugs, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the drug;
- Bionomics may be required to recall a drug or change the way such drugs are administered to patients;
- additional restrictions may be imposed on the marketing or the manufacturing of the particular drug;
- Bionomics may be required to implement changes to the manufacturing processes for the drug or any component thereof;
- regulatory authorities may require the addition of labelling statements, such as a “black box” warning or a contraindication;
- Bionomics may be required to implement a risk evaluation and mitigation strategy, or REMS, or create a medication guide outlining the risks of such side effects for distribution to patients;
- Bionomics could be sued and held liable for harm caused to patients;
- the drug may become less competitive; and
- Bionomics' reputation may suffer.

Any of the foregoing events could also prevent Bionomics from achieving market acceptance of the particular drug candidate, and, if approved, and result in loss of significant revenues, which would materially and adversely affect its results of operations and business.

# Key risks – industry specific (cont.)

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| Risk of misconduct or non-compliance with regulatory standards | Bionomics is exposed to the risk that its employees, independent contractors, clinical investigators, CROs, CMOs, consultants, vendors and collaboration partners may engage in fraudulent conduct or other illegal activities. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions Bionomics may take to detect and prevent misconduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting itself from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. |
| Ongoing regulatory risks | Any regulatory approvals that Bionomics receives for its drug candidates may be subject to limitations on the approved indicated uses for which the drug may be marketed or the conditions of approval, or contain requirements for potentially costly post-market testing and surveillance to monitor the safety and efficacy of the drug candidate.<br><br>Later discovery of previously unknown problems with Bionomics' drug candidates, including side effects of unanticipated severity or frequency, or with its third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:<br>• restrictions on the marketing or manufacturing of its drug candidates, withdrawal of the drug from the market, or voluntary or mandatory drug recalls;<br>• fines, warning letters or holds on clinical trials;<br>• refusal by the FDA or other regulatory authorities to approve pending applications or supplements to approved applications filed by Bionomics or suspension or revocation of approvals;<br>• drug seizure or detention, or refusal to permit the import or export of Bionomics' drug candidates; and<br>• injunctions or the imposition of civil or criminal penalties. |

# Key risks – industry specific (cont.)

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| Ongoing regulatory risks (cont.) | The FDA and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of Bionomics' drug candidates. Bionomics cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or other jurisdictions. If Bionomics is slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if it is not able to maintain regulatory compliance, Bionomics may lose any marketing approval that it may have obtained and may not achieve or sustain profitability. |
| Intellectual property rights and enforcement risks | Bionomics' success will depend, in part, on its ability to obtain and maintain intellectual property rights in the United States and other countries, successfully defend its intellectual property rights against third party challenges and successfully enforce its intellectual property rights to prevent third party infringement. Bionomics relies upon a combination of patents, trade secret protection and confidentiality agreements.<br><br>Bionomics' ability to protect any of its drug candidates and technologies from unauthorised or infringing use by third parties depends in substantial part on its ability to obtain and maintain valid and enforceable patents in both the United States and other countries. Although Bionomics' patent portfolio includes patents and patent applications in the United States, Europe, Canada and Australia, the scope of coverage provided by these patents varies from country to country.<br><br>There can be no assurance that Bionomics will discover or develop patentable drugs or processes or that patents will issue from any pending patent applications owned or licensed by it or any patent applications it may own or license in the future, or if issued, that the breadth of such patent coverage will be sufficient. Bionomics cannot guarantee that claims of issued patents owned or licensed to it, either now or in the future, are or will be held valid or enforceable by the courts or, even if unchallenged, will provide Bionomics with exclusivity or commercial value for its drug candidates or technology or any significant protection against competitive drugs or prevent others from designing around Bionomics' claims. |

# Key risks – industry specific (cont.)

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| Intellectual property rights and enforcement risks (cont.) | Further, if Bionomics encounters delays in regulatory approvals, the period of time during which it could market any future drugs under patent protection could be reduced. Bionomics will incur significant ongoing expenses in maintaining its patent portfolio. Should Bionomics lack the funds to maintain its patent portfolio or to enforce its rights against infringers, it could be adversely impacted. Even if claims of infringement are without merit, any such action could divert the time and attention of management and impair Bionomics' ability to access additional capital or cost it significant funds to defend. |
| Reimbursement risk | The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payers are essential for most patients to be able to afford drugs such as Bionomics' drug candidates, assuming approval. Bionomics' ability to achieve acceptable levels of coverage and reimbursement for drugs by governmental authorities, private health insurers and other organisations will have an effect on its ability to successfully commercialise, and attract additional collaboration partners to invest in the development of its drug candidates. Bionomics cannot be sure that coverage and reimbursement in the United States, the European Union, Australia or elsewhere will be available for any drug that it may develop, and any reimbursement that may become available may be decreased or eliminated in the future.<br><br>If reimbursement is not available or is available only at limited levels, Bionomics may not be able to successfully commercialise its drug candidates, and may not be able to obtain a satisfactory financial return on drugs that it may develop. |

# Key risks – general risks

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| Economic | General economic conditions, introduction of tax reform, new legislation, movements in interest and inflation rates and currency exchange rates may have an adverse effect on Bionomics' activities, as well as on its ability to fund those activities. |
| Competition risk | The industry in which Bionomics is involved is subject to domestic and global competition. Although Bionomics will undertake all reasonable due diligence in its business decisions and operations, Bionomics has no influence or control over the activities or actions of its competitors, which activities or actions may, positively or negatively, affect the operating and financial performance of Bionomics' projects and business. To the extent that there are new entrants or changes in strategy by existing competitors, Bionomics' competitive position may be impacted by consequent adverse effects on the operating and financial performance of Bionomics' projects and business. |
| Market for shares | The price of the New Shares is subject to uncertainty and there can be no assurance that an active market for Bionomics' Shares will continue after the Equity Raising. The price at which the New Shares trade on ASX may be higher or lower than the issue price of the New Shares offered under this Equity Raising and could be subject to fluctuations in response to variations in operating performance and general operations and business risk, as well as external operating factors over which the Directors and Bionomics have no control, such as movements in exchange rates, changes to government policy, legislation or regulation and other events or factors.<br><br>There can be no guarantee that an active market in Bionomics' Shares will continue or that the price of the New Shares will increase. There may be relatively few or many potential buyers or sellers of Bionomics' Shares on ASX at any given time. This may increase the volatility of the market price of the New Shares. It may also affect the prevailing market price at which Shareholders are able to sell their New Shares. This may result in Shareholders receiving a market price for their New Shares that is above or below the price that Shareholders paid. |

# Key risks – general risks (cont.)

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| Market conditions | Share market conditions may affect the value of Bionomics' Shares regardless of Bionomics' operating performance. Share market conditions are affected by many factors such as:<br>• general economic outlook;<br>• introduction of tax reform or other new legislation;<br>• interest rates and inflation rates;<br>• changes in investor sentiment toward particular market sectors;<br>• the demand for, and supply of, capital;<br>• pandemic or global health crises; and<br>• terrorism or other hostilities.<br>The market price of Shares can fall as well as rise and may be subject to varied and unpredictable influences on the market for equities in general and biopharmaceutical stocks in particular. Neither Bionomics nor the Directors warrant the future performance of Bionomics or any return on an investment in Bionomics. |
| Taxation | The acquisition and disposal of New Shares will have tax consequences, which will differ depending on the individual financial affairs of each investor. All potential investors in the New Shares are urged to obtain independent financial advice about the consequences of acquiring New Shares from a taxation viewpoint and generally. To the maximum extent permitted by law, Bionomics, its officers and each of their respective advisors accept no liability and responsibility with respect to the taxation consequences of subscribing for New Shares under this Equity Raising. |
| Investment speculative | The above list of risk factors ought not to be taken as exhaustive of the risks faced by Bionomics or by investors in Bionomics. The above factors, and others not specifically referred to above, may in the future materially affect the financial performance of Bionomics and the value of the New Shares offered under this Equity Raising. Therefore, the New Shares to be issued pursuant to the Equity Raising carry no guarantee with respect to the payment of dividends, returns of capital or the market value of those New Shares.<br>Potential investors should consider that the investment in Bionomics is highly speculative and should consult their professional advisers before deciding whether to apply for New Shares. |

# Appendix B

# International Offer Restrictions

# International offer restrictions

**Important Information**

This document does not constitute an offer of New Shares in any jurisdiction in which it would be unlawful. In particular, this document may not be distributed to any person, and the New Shares may not be offered or sold, in any country outside Australia and New Zealand except to the extent permitted below.

**European Union (Germany and Malta)**

This document has not been, and will not be, registered with or approved by any securities regulator in Germany and Malta. Accordingly, this document may not be made available, nor may the New Shares be offered for sale, in Germany and Malta except in circumstances that do not require a prospectus under Article 1(4) of Regulation (EU) 2017/1129 of the European Parliament and the Council of the European Union (**Prospectus Regulation**). In accordance with Article 1(4)(a) of the Prospectus Regulation, an offer of New Shares in Germany and Malta is limited to persons who are "qualified investors" (as defined in Article 2(e) of the Prospectus Regulation).

**United Kingdom**

Neither this document nor any other document relating to the Equity Raising has been delivered for approval to the Financial Conduct Authority in the United Kingdom and no prospectus (within the meaning of section 85 of the Financial Services and Markets Act 2000, as amended (**FSMA**)) has been published or is intended to be published in respect of the New Shares. This document is issued on a confidential basis to "qualified investors" (within the meaning of section 86(7) of the FSMA) in the United Kingdom, and these securities may not be offered or sold in the United Kingdom by means of this document, any accompanying letter or any other document, except in circumstances which do not require the publication of a prospectus pursuant to section 86(1) of the FSMA. This document should not be distributed, published or reproduced, in whole or in part, nor may its contents be disclosed by recipients to any other person in the United Kingdom. Any invitation or inducement to engage in investment activity (within the meaning of section 21 of the FSMA) received in connection with the issue or sale of the New Shares has only been communicated or caused to be communicated and will only be communicated or caused to be communicated in the United Kingdom in circumstances in which section 21(1) of the FSMA does not apply to Bionomics.

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**United States**

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