



DIVISION OF  
CORPORATION FINANCE

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

October 8, 2021

Errol De Souza  
Executive Chairman  
Bionomics Limited/FI  
200 Greenhill Road  
Eastwood SA 5063  
Australia

**Re: Bionomics Limited/ FI  
Draft Registration Statement on Form F-1  
Submitted September 10, 2021  
CIK No. 0001191070**

Dear Mr. Souza:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

DRS Form F-1 filed September 10, 2021

Cover Page

1. We note your statement that the closing price of your ordinary shares on the Australian Securities Exchange was A\$ \_\_\_\_\_ per ordinary share, equivalent to a price of US\$ \_\_\_\_\_ per ADS. You may use the most recent home market trading price, converted to U.S. dollars at the most recent exchange rate, assuming the U.S. IPO price will be largely based on the home market trading price. If you expect that the U.S. IPO price will not be substantially the same as the home market trading price, please disclose on the cover page of the preliminary prospectus a bona fide price range of the offered securities.

BNC210, page 2

2. Please revise the summary to discuss briefly the federal and state regulation of your combination of BNC210 and EMP-01 as a controlled substance. Please also include any related risk in your bulleted risks listed on page 4.
3. We note that you received Fast Track designation from the FDA for your PTSD program. Please balance this with disclosure that such designation may not result in a faster development process and does not assure approval by the FDA.

Our Portfolio, page 2

4. We note the inclusion of undisclosed product candidates relating to the treatment of pain and cognition in your pipeline table. Given the limited amount of disclosure related to these programs, please explain why these programs are sufficiently material to your business to warrant inclusion in your pipeline table. If they are material, please expand your disclosure in your Business section to provide a more fulsome discussion of these programs, including a description of preclinical studies or development activities conducted. Alternatively, remove any programs that are not currently material from your pipeline table on pages 2 and 106. Please also identify the two product candidates that are in Phase 1 development under the Merck collaboration.

Legacy Oncology Programs, page 3

5. Please quantify the amount of payments you have received to date under the license agreement with Carina Biotech and the current stage of development of BNC101 under the agreement.

Our Early-Stage CNS Assets, page 3

6. We note your statement that your early stage programs are at a similar stage to the stage at which the a7 receptor PAM program was licensed under the 2014 Merck License Agreement. Please balance this disclosure with the fact that there is no guarantee that these programs will ever be licensed out.

a7 Receptor PAM Program with Merck, page 3

7. We note the statement that you are eligible to receive up to US\$465 million in milestone payments for achievement of certain development and commercial milestones. Please disclose that because Merck controls the clinical development and worldwide commercialization of any products developed from the collaboration, you cannot predict whether or when you might achieve any milestone payments under the collaboration or estimate the full amount of such payments, and that you may never receive any such payments. Additionally, please disclose you will not receive any royalty payments from Merck as a result of the contingent value right to be issued for the sole benefit of your existing shareholders. Please also explain the extent to which you have access to

information related to clinical trial results, serious adverse events and ongoing communications with the FDA relating to these programs or the extent to which Merck is required to provide you with this information.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company, page 5

8. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

Dilution, page 88

9. Please revise your definition of net tangible book value to more clearly explain your calculation of net tangible book value and per share information.

Licenses and Collaboration, page 94

10. We note your disclosure here and on page 127 that Merck is required to make tiered royalty payments on a product-by-product and country-by-country basis, ranging from mid single-digit to low double-digit percentage royalty rates. Please refine your disclosure to provide a more exact description of the high end of the range (e.g., low teens) to ensure that you have described the royalty rate within a ten percentage point range.

Management's Discussion and Analysis of Financial Condition and Results of Operations

Results of Operations, page 98

11. Please revise your discussion of other income on page 99 to quantify the impact for each of the factors you cited for the change in the amounts between the years ended June 30, 2020 and June 30, 2021.

Business

Overview, page 106

12. You make several assertions regarding the safety and efficacy of your product candidates. Safety and efficacy determinations are solely within the authority of the FDA (or applicable foreign regulator). You may present clinical trial end points and objective data resulting from trials without concluding efficacy and you may state that your product candidates have been well tolerated, if accurate. Please revise or remove statements/inferences throughout your prospectus that your product candidates are safe and/or effective. As a non-exhaustive list of illustrative examples only, we note the following:
  - On page 107, you state "BNC210 has...demonstrated anti-anxiety and antidepressant effects..."

- On page 107, you refer to an extensive safety database.
- On page 107, you state "[W]e have observed three key anxiety-reducing features associated with BNC210:
  - statistically significant reductions in hyperactivity in the amygdala, the region of the brain responsible for emotional control, when exposed to fear-inducing triggers;
  - in a head-to-head study, showed a statistically significant reduction in the intensity of defensive behavior, while lorazepam, a widely prescribed benzodiazepine did not; and
  - a statistically significant reduction in the intensity and total number of panic symptoms as well as more rapid recovery from the panic state relative to placebo
- On page 107, you state "a target blood exposure predicted to show clinically meaningful benefit for patients suffering from PTSD."
- On page 109, you reference "favorable safety data" when discussing BNC210.
- On page 114, you state BNC210 has the potential for "similar clinical efficacy without many of the limiting side effects observed with benzodiazepines, SSRIs and SNRIs."
- On page 125, you state "Representative molecules from each series have been observed to reverse pharmacologically induced cognitive deficits in mouse and rat models with equivalent efficacy to risperidone, an antipsychotic drug used to treat schizophrenia, used as the positive control."
- On page 125, you state "Preclinical studies showed BNC101 was able to target and reduce the frequency of cancer stem cells derived from primary patient colorectal tumors both *in vitro* and *in vivo*."

Legacy Oncology Program, page 108

13. We note that you have a license agreement with Carina Biotech and a collaboration agreement with EmpathBio. Please provide the license and collaboration agreements as exhibits, and please revise the descriptions of these agreements to disclose:
- each parties' rights and obligations under the agreement;
  - quantify all payment made to date;
  - disclose separately the aggregate amount of all potential development, regulatory and commercial milestone payments;
  - disclose the amount of option fees for additional targets;
  - quantify the royalty rate, or a range no greater than 10 percentage points per tier;
  - disclose when royalty provisions expire, if the expiration is based on a number of years following commercialization, disclose the number of years;
  - disclose the expiration date; and
  - describe any termination provisions.

Our Strategy, page 109

14. We note your disclosure here and throughout your prospectus regarding your goal of developing and commercializing "novel, first-in-class" treatments. Please remove references to "first-in-class" as this statement implies an expectation of regulatory approval and is inappropriate given the length of time and uncertainty with respect to securing marketing approval. If your intention is to convey your belief that your platform or your programs utilize a novel technology or approach, you may discuss how your technology differs from technology used by competitors or that you are not aware of competing products that are further along in the development process. Statements such as these should be accompanied by cautionary language that the statements are not intended to give any indication that your technology or any potential product candidates have been proven effective or will receive regulatory approval.
15. We note your disclosure here and in the Summary that your strategy is to "rapidly progress" clinical development for your BNC210 product. Please revise these statements and any similar disclosure to remove any implication that you will be successful in commercializing your product candidates in a rapid or accelerated manner as such statements are speculative.

Potential Advantages of BNC210 for the Treatment of Anxiety and Stressor-Related Disorders, page 114

16. Please remove the table on page 115 regarding BNC210 vs. current therapies. The table implies an expectation of regulatory approval and is inappropriate given the early stage of development of BNC210.

Clinical Development of BNC210, page 115

17. Please revise your graphics throughout pages 119-122 so that they are large enough to be legible for investors.
18. Please provide p-values for the results of your trials or explain why you are unable to provide such values. At first use, please provide a brief explanation of the disclosed p-value and how it is used to measure statistical significance.

Intellectual Property, page 128

19. We note your statements that you have patented 1) two series of small molecule inhibitors with functional selectivity for Nav1.7 and Nav1.8 voltage gated sodium channels for the treatment of chronic pain and 2) two series of small molecule Kv3.1/3.2 potassium channel activators for the potential treatment of cognitive deficits and negative symptoms in schizophrenia and for the treatment of autism spectrum disorders. Please expand your Intellectual Property section to include descriptions of these patents.

Errol De Souza  
Bionomics Limited/FI  
October 8, 2021  
Page 6

Principal Shareholders, page 162

20. Please identify the natural person or persons who directly or indirectly exercise sole or shared voting and/or dispositive power with respect to the common stock held by BVF Partners L.P. and Apeiron Investment Group Ltd.

Consolidated Financial Statements , page F-3

21. You disclose in Note 2(ii) that all amounts in the financial statements are presented in Australian dollars. Please state the currency on the face of the financial statements as you have done elsewhere in the filing and as required under Rule 3-20 of Regulation S-X.

Notes to the Financial Statements

Note 2: Summary of Significant Accounting Policies

(iii) Application of New and Revised Accounting Standards , page F-9

22. You stated on page 6 that you are an Emerging Growth Company ("EGC") and elected to take advantage of an extended transition period for complying with new or revised accounting standard. We further note you adopted all the new and revised Standards and Interpretations issued by the IASB and effective for an accounting period that begins on or after July 2020. However, the EGC accounting deferral is not applicable to IFRS filers. Refer to the cover page of Form F-1, and please revise accordingly.

You may contact Christie Wong at 202-551-3684 or Kevin Vaughn at 202-551-3494 if you have questions regarding comments on the financial statements and related matters. Please contact Jordan Nimitz at 202-551-6001 or Christopher Edwards at 202-551-6761 with any other questions.

Sincerely,

Division of Corporation Finance  
Office of Life Sciences

cc: Nathan Ajiashvili, Esq.