



DIVISION OF  
CORPORATION FINANCE

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

March 12, 2015

Via E-mail

Jon Congleton  
President and Chief Executive Officer  
Nivalis Therapeutics, Inc.  
3122 Sterling Circle  
Suite 200  
Boulder, Colorado 80301

**Re: Nivalis Therapeutics, Inc.  
Draft Registration Statement on Form S-1  
Submitted on February 13, 2015  
CIK No. 0001626199**

Dear Mr. Congleton:

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.

Table of Contents

1. We note your statements on the bottom of the Table of Contents page that your internal research "has not been verified by any independent source." Please remove this statement from your registration statement as it acts as an inappropriate disclaimer on the accuracy of the information provided in the prospectus.

Prospectus Summary, page 1

2. Please revise your disclosure to explain the meaning or significance of the following terms at their first use in the prospectus:

- S-nitrosoglutathione, or GSNO
  - GSNO reductase, or GSNOR
  - chaperone proteins
  - correctors
  - potentiators
  - co-formulated
  - non-formulated
3. Please revise your disclosure in the prospectus summary to discuss the current regulatory status of lumacaftor/ivacaftor at your first reference to these products. In addition, please explain what the PDUFA date refers to with respect to the timing of FDA approval. Please also address the possibility that the FDA may determine not to approve lumacaftor/ivacaftor at the time of the PDUFA date.

Our Risks, page 3

4. Please expand the bulleted list to discuss the unique risks and challenges related to the your reliance on lumacaftor/ivacaftor to advance your primary product candidate including:
- the risk that Vertex is unable to, or decides not to, obtain approval or proceed with its commercial launch of lumacaftor/ivacaftor;
  - the risks posed by the lack of any agreements with Vertex regarding the use of lumacaftor/ivacaftor in the development of N91115;
  - the potential availability or lack thereof of patients treated with lumacaftor/ivacaftor available for Phase 2 clinical trials of N91115

Risk Factors

“N91115 or any other potential product candidate may cause adverse events...” page 21

5. We note your risk factor disclosure that undesirable adverse events caused by N91115 or any other potential product candidate could cause you or regulatory authorities to interrupt, delay, halt or terminate clinical trials. In the Business section of your prospectus please identify whether any subjects in your trials have experienced severe adverse events in connection with administration of N91115 in your clinical trials.

Research and Development Expense, page 68

6. Please revise the table on page 69 to further breakout total personnel and other expenses by the types of costs included thereto (i.e. personnel-related costs, consulting, travel, lab supplies, depreciation, stock-based compensation, and miscellaneous expenses).

Valuation of Our Common Stock, page 80

7. Please disclose the method you used in determine the fair value of your common stock (i.e. market approach, income approach, or asset-based approach).
8. Please provide us a table that details the terms of all equity issuances, including options, warrants, ordinary shares, preferred shares, and convertible instruments subsequent to September 30, 2014. The terms should include the number of ordinary shares underlying the instrument, ordinary share fair value on the grant date, and exercise price.
9. We may have additional comments on your accounting for equity issuances including stock compensation, underwriter and preferred stock warrant liability, and beneficial conversion features. Once you have an estimated offering price, please provide us an analysis explaining the reasons for the differences between recent valuations of your common stock leading up to the IPO and the estimated offering price.

Business, page 89

10. Please disclose, where applicable in your business section, when an investigational new drug application (“IND”) was filed for the commencement of clinical trials for N91115.

Ussing Chamber Experiments in Homozygous F508del CFTR HBE Cell, page 99

11. We note your disclosure that the addition of N91115 to lumacaftor and ivacaftor resulted in a statistically significant, 1.7 times increase in AUC compared to lumacaftor and ivacaftor alone, with a p value of 0.003. Please define the term “statistically significant” and explain what a “p value” indicates about the significance of your results.

Other Comments

12. Please submit all exhibits as soon as practicable. We may have further comments upon examination of these exhibits.
13. Please confirm that the graphics included in your registration statement are the only graphics you will use in your prospectus. If those are not the only graphics, please provide any additional graphics prior to their use for our review.
14. 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.

You may contact at Sharon Blume at (202) 551-3474 or Keira Nakada at (202) 551-3659 if you have questions regarding comments on the financial statements and related matters.

Jon Congleton  
Nivalis Therapeutics, Inc.  
March 12, 2015  
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Please contact Tara Keating Brooks at (202) 551-8336, Bryan Pitko at (202) 551-3203 or me at (202) 551-3715 with any other questions.

Sincerely,

*/s/ Bryan J. Pitko* for

Jeffrey P. Riedler  
Assistant Director

cc: Via E-mail  
Laura I. Bushnell  
King & Spalding LLP