



DIVISION OF
CORPORATION FINANCE

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

May 5, 2015

Nick Glover
President and Chief Executive Officer
ProNAi Therapeutics, Inc.
2150 – 885 West Georgia Street
Vancouver, British Columbia
Canada V6C 3E8

**Re: ProNAi Therapeutics, Inc.
Draft Registration Statement on Form S-1
Submitted April 8, 2015
CIK No. 0001290149**

Dear Mr. Glover:

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.

General

1. Prior to printing and distribution of the preliminary prospectus, please provide us with mock-ups of any pages that include any pictures or graphics to be presented. Accompanying captions, if any, should also be provided. We may have comments after reviewing the materials.
2. 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.

Prospectus Summary, page 1

Overview, page 1

3. We note your disclosure in the second risk factor on page 11 that your only product candidate, PNT2258, is in the early stage of development. Please revise the first paragraph to provide similar disclosure. Please clarify in the summary any FDA or other regulatory approvals you have received to do your clinical trials, if applicable. Also, please disclose in one of the opening paragraphs that you do not currently have any products in the market and that before you can legally distribute and market your products you must receive regulatory approvals, such as from the FDA or similar regulatory agencies, and you have not yet received any such regulatory approvals. Please also briefly mention the potentially lengthy process you may need to undertake before you can get any products through clinical trials and to the market.
4. Please revise this section to disclose that your auditors have issued a going concern opinion on your audited financial statements. Please also disclose in one of the opening paragraphs that you have not generated revenue and have incurred losses since inception. Please also revise to disclose your cash on hand as of the most recent practicable date and your monthly “burn rate” post-offering. Additionally, please revise to quantify the amounts needed to continue operations and to fund your planned clinical trials as detailed on page 3. Please also revise the risk factor on page 15 and the Future Capital Requirements section on page 67 accordingly.

Our Lead Product Candidate: PNT2258, page 2

5. Please refer to the third paragraph. We note your disclosure that you may seek “accelerated registration paths” and may apply for “orphan drug, breakthrough therapy, fast track or other regulatory designations.” Please revise to add balancing language that PNT2258 has not obtained any accelerated registration approval or regulatory designation and there is no guarantee that PNT2258 will obtain any accelerated registration approval or regulatory designation in the future.
6. Please refer to the third and fourth paragraphs. We note your development program anticipates one ongoing and four planned Phase 2 trials for PNT2258. Please revise to briefly discuss the costs and time required to complete each trial. To the extent that you will need additional funds to complete these trials, please revise to make that clear.
7. We note your disclosure on page 63 that the “expected net proceeds from this offering, together with [your] exiting cash and cash equivalents and short-term investments, will not be sufficient for [you] to complete development of [your] lead product candidate.” Please revise the fifth paragraph to provide similar disclosure.

8. Please indicate in this section that the other product candidates that you are developing are based on technology similar to PNT2258, so any issues you may face may also apply to your other product candidates, as you disclose on page 12.

Maximize the Global Commercial Value of PNT2258, page 4

9. Please revise this bullet to disclose your license agreements with Marina and Novosom to include briefly discussing the associated milestone and royalty payments.

Risk Factors, page 11

If we fail to obtain additional capital, page 15

10. Please refer to the second paragraph. Please include in a separate risk factor, with its own separate subheading, that your auditors have issued a going concern opinion on your audited financial statements.

If we encounter difficulties enrolling patients in our clinical trials, page 16

11. We note that you currently have one ongoing trial, Wolverine, that your first patient was enrolled in December of 2014 and that the trial calls for 60 patients. Please advise regarding the current status of patient enrollment for the Wolverine trial and update your disclosure, as may be applicable.

If we fail to comply with our obligations under any license, page 45

12. We note your disclosure on pages 62 and 63 that you will owe Marina certain milestone payments and royalty payments in connection with DNAi product candidates other than PNT2258 and that you will owe Novosom certain milestone payments and royalty payments in connection with PNT2258. Please revise this risk factor to disclose these milestone and royalty payments so that investors can assess the discussed risk.

Use of Proceeds, page 53

13. Please refer to the second paragraph and the disclosed principal purposes for which the net proceeds will be used. Please revise to quantify the approximate amount intended to be used for each such purpose. Refer to Item 504 of Regulation S-K. Also, to the extent practicable, please indicate the anticipated amount of the use of proceeds for each of the phases of the trials listed in the first bullet point or advise.

14. We note your disclosure here that you plan to use certain of the net proceeds to “make significant investments in the clinical and manufacturing activities related to PNT2258” to include supporting ongoing and future trials. To the extent material amounts of other funds are necessary to accomplish this purpose, please revise to state the amounts of other funds needed to accomplish this purpose and the sources thereof. Please also revise the other disclosed principal purpose bullets accordingly. Refer to Instruction 3 of Item 504 of Regulation S-K.

Management’s Discussion and Analysis of Financial Condition, page 62

Overview, page 62

15. We note your disclosure on pages 62 and 63 that you will owe Marina certain royalty payments in connection with DNAi product candidates other than PNT2258 and that you will owe Novosom certain royalty payments in connection with PNT2258. In both cases with respect to royalty payments, your disclosure indicates that these are low single-digit royalties. Please revise to specifically quantify these royalty payments or advise. Please also revise the License and Payment Agreements section on page 90 accordingly.

Business, page 74

16. Please expand this section to provide more detail regarding the timeline and steps involved in developing, obtaining regulatory approval and commercializing PNT2258, including anticipated costs for each step. To the extent additional financing is needed, and may not be available, please also make that clear.

Status of Our Clinical Development Program, page 83

17. Please indicate the geographic location of these trials, such as the United States.

Clinical Development Strategy, page 87

PNT2258-03 Wolverine Trial in Relapsed or Refractory DLBCL, page 88

18. Please revise to discuss in greater detail the costs and time required to complete this trial. In this regard, we note that you anticipate multiple clinical data read-outs over the next 12 to 24 months. We also note that you are looking to collect data on 60 patients and that timing could be affected by patient enrollment. Please revise to include enough detail so investors can clearly understand the costs and time required to complete this trial. Please also revise the descriptions of your other planned trials accordingly.

Nick Glover
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Page 5

Government Regulation, page 94

FDA Approval Process, page 94

19. Please discuss where you are in the FDA approval process. Please revise this section to clarify the status of your existing IND, including FDA approval, and whether such IND covers all of your planned trials as discussed on page 3.

20. Please revise this section to disclose your current cost and time estimate of obtaining FDA approval for PNT2258.

Principal Stockholders, page 120

21. Please revise to provide the required information as of the most recent practicable date. Refer to Item 403 of Regulation S-K.

Description of Capital Stock, page 123

22. Please refer to the first paragraph. Please delete the phrase “and to the applicable provisions of Delaware law” from the last sentence.

You may contact Effie Simpson at (202) 551-3346 or Jean Yu, Assistant Chief Accountant, at (202) 551-3305 if you have questions regarding comments on the financial statements and related matters. Please contact Donald E. Field at (202) 551-3680 or me at (202) 551-3210 with any other questions.

Sincerely,

/s/ Susan Block

Susan Block
Attorney-Advisor

cc: Stephen M. Graham, Esq.
Fenwick & West LLP