



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

DIVISION OF  
CORPORATION FINANCE

Mailstop 4720

July 13, 2016

Mats Blom  
Senior Vice President, Chief Financial Officer  
Zealand Pharma A/S  
Smedeland 36  
2600 Glostrup (Copenhagen)  
Denmark

**Re: Zealand Pharma A/S  
Draft Registration Statement on Form F-1  
Submitted June 16, 2016  
CIK No. 0001674988**

Dear Mr. Blom:

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.

[Prospectus Summary, page 1](#)

[Our Product Pipeline, page 2](#)

1. The table of your pipeline product candidates on pages 2 and 88 should reflect the actual, and not the anticipated, status of your pipeline candidates as of the latest practicable date. The table currently suggests that Lixisenatide – US and iGlarLixi have completed regulatory review but your disclosure says that both product candidates are still under regulatory review. Similarly, the table suggests that ZP4207 (single-dose glucagon) has completed Phase 2 clinical trials, when your disclosure states that the product candidate is currently in a Phase 2 clinical trial. Finally, please either identify the “undisclosed biological target” or remove it,

along with the “several peptide projects and indications,” from the table. The table is intended to provide information about your product candidates in development that are reasonably likely to result in an approved product in the foreseeable future. Unless an indication and a compound have been identified, the product is too preliminary for inclusion in the table.

2. Please include a discussion of Elsiglutide and ZP2929 in your Prospectus Summary. Please also disclose that the FDA placed the ZP2929 IND on full clinical hold, BI returned the product candidate to you, and you have not yet determined whether to advance ZP2929 further.
3. We note your disclosure on page three that you “intend to invest substantially all of the future milestone and royalty payments” into further growing and advancing your proprietary pipeline. We also note your disclosure on page five that you expect near-term royalty and milestone payments from your out-licensed portfolio of treatments and peptide-based product candidates. However, it appears that a substantial portion of your near-term royalty and milestone payments will either be used to repay the ZP SPV Notes, will be placed in a collateral reserve account, and or will be paid to Alkermes. Please include balanced disclosure in this section so that investors are aware of the restrictions on your use of royalty and milestone payments and please disclose the percentage of total milestone and royalty payments to date that have been reserved or used as payment for obligations.

Risks Associated with Our Business, page 5

4. In the first bullet point under “Risks Associated with Our Business,” please quantify your operating losses for the most recent fiscal year.

Use of Proceeds, page 56

5. Please revise your disclosure in this section to indicate how your use of proceeds from the offering will be allocated towards the clinical development for each of ZP1848, ZP4207 as a single-dose rescue treatment for acute, severe hypoglycemia and ZP4207 as a multiple-dose version for use in a dual-hormone artificial pancreas system, respectively. In particular, please indicate whether the anticipated proceeds will be sufficient to fund all three product candidates through clinical development and registration. If not, please give the order of priority for each of the product candidates as well as the amount and sources of other funds needed. Refer to Item 3.C.1. of Form 20-F.

Management  
Compensation

Executive Management Agreements, page 138

6. Please file each executive management agreement discussed in this section as an exhibit to the registration statement. Alternatively, please advise us if you are relying on an exception to Item 601(b)(10)(iii)(A) of Regulation S-K.

Management's Discussion and Analysis and Results of Operations, page 64

ZP SPV Notes (Royalty Bond)

7. We note that the ZP SPV Notes are secured by 86.5% of annual royalty payments from sales of lixisenatide received under the Sanofi License Agreement and that you are also obligated to place milestone payments in respect of lixisenatide and iGlarLixi in a collateral reserve account. Please disclose the amount of milestone payments to date that have been placed in the reserve account and the percentage this represents of total milestones received to date. Please also clarify whether you are obligated to pay all (or any portion of) the royalty payments you receive toward the ZP SPV Notes, and, if so, the amount you have paid to date and the percentage this represents of total royalty amounts received by you. Please also disclose the approximate length of time that you believe you will be obligated to devote milestone and/or royalty payments to the ZP SPV Notes. Please include similar disclosure in your risk factor on page 17.

Business, page 87

8. For each product candidate discussed, please disclose when investigational new drug applications ("INDs") were filed for the commencement of clinical trials, the name of the trial sponsors and the subject of the INDs. If an IND was not filed pertaining to any of your clinical trials, please explain why an IND was not required.

Summary of Our Out-Licensed Products and Product Candidates

Other Out-Licensed Product Candidates, page 89

9. Please explain the concept of "statistical significance" at its first use on page 89. Please also explain how "p-value" is used to measure statistical significance.

Our Growth Strategies, page 92

10. We note your statement on page 93 that you have applied for orphan status in the United States and in some European countries. Please briefly explain the eligibility criteria and significance of orphan drug designation by the FDA and EMA.

Our Out-Licensed Product Candidates, page 95  
Proprietary Pipeline of Product Candidates, page 104

11. Please ensure that your disclosure throughout these sections includes the primary and secondary endpoints for the completed clinical trials, as applicable, and conclusions as to statistical significance of such endpoints.

ZP4207 for Hypoglycemia, page 108

12. We note in this section that you provide graphics and preclinical data “from an early lead candidate ZP-GA-1, which has a similar formulation to ZP4207.” Please disclose the particular relevance of this data to ZP4207, including whether this data will be considered by the FDA or any other regulatory agency in determining whether to grant approval to ZP4207.
13. We note that in several places in your prospectus you refer to prior clinical studies of ZP4207 and you characterize the drug as “safe.” For example, you state on page 110 that the results of the ZP4207 Phase 1a clinical trial showed that ZP4207 was “safe.” Because regulatory approval of ZP4207 is dependent on the FDA making a statutory finding that a drug is both safe and effective enough to be approved for commercial sale, it is premature for you to describe ZP4207, in any of the dosages administered, as safe. Accordingly, please delete the language stating that ZP4207 is safe throughout your prospectus, as applicable. You may include a statement, if true, to the effect that no serious adverse side-effects have been observed in clinical studies or that the drug has been observed to be generally well-tolerated in clinical trials.

Material Contracts, page 114

Sanofi License Agreement for Lixisenatide and iGlarLixi, page 114

14. We note your statements here and throughout the prospectus that you are eligible to earn “low double digit percentage royalty payments” under this agreement. Please revise your description of royalty rates to provide a range that does not exceed ten percent (e.g., between twenty and thirty percent).
15. We note your disclosure regarding counterclaims brought by AstraZeneca regarding patent infringement for products that contain lixisenatide. Please disclose the current status of this litigation.

Licensing Agreements with Boehringer Ingelheim for Glucagon/GLP-1 dual agonists, page 115

16. We note your statements here and throughout the prospectus that you are eligible to earn “royalties ranging from high single to low double digit percentages” under the 2011 BI Agreement and “royalties in the mid-single to low double digit percentages” under the 2014

BI Agreement. Please revise your description of royalty rates to provide a range that does not exceed ten percent (e.g., between twenty and thirty percent).

17. We note your statement that “[t]he 2011 BI Agreement continues for as long as BI’s royalty obligations continue, unless earlier terminated.” Please revise your description of this agreement to clarify the royalty term. Please make corresponding changes to your discussion of the 2014 BI Agreement.

Licensing Agreement with Helsinn for Elsiglutide, page 116

18. Please disclose the aggregate potential milestone payments under this agreement.

Certain Material U.S. Federal Income Tax Considerations, page 169

Certain Material Danish Income Tax Considerations, page 174

19. Please remove the word “Certain” from the heading in this section as it may imply that you have not addressed all material tax consequences. Refer to Staff Legal Bulletin No. 19.

Financial Statements

Statements of Changes in Equity, page F-7

20. Tell us why you present retained earnings when you are incurring losses and why you do not present share premium separate from retained earnings for capital increases and warrants issued.

Notes to Financial Statements

Revenue from Boehringer Ingelheim, page F-21

21. You state “In 2014, we received DKK 37.3 million in revenue from milestone payments from BI in connection with the signing of the 2014 BI License Agreement.” Please provide us with your analysis supporting immediate revenue recognition and not deferral of the revenue at signing with recognition over the term of the agreement.

Exhibits

22. Please file the indenture and any other instruments defining the rights of holders of the ZP SPV Notes as exhibits to the registration statement, or, in the alternative, tell us why you do not believe you are required to do so. See Item 601(b)(4) of Regulation S-K.
23. Please file copies of your collaboration agreement with Beta Bionics, Inc. and your agreement to pay Alkermes a percentage of payments received on lixisenatide, as exhibits to the registration statement, or, in the alternative, tell us why you do not believe you are required to do so. See Item 601(b)(10) of Regulation S-K.

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General

24. 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 Tabatha McCullom at (202) 551-3658 or Lisa Vanjoske at (202) 551-3614 if you have questions regarding comments on the financial statements and related matters. Please contact Christina Thomas at (202) 551-3577 or Erin Jaskot at (202) 551-3442 with any other questions.

Sincerely,

*/s/ Erin K. Jaskot, for*

Suzanne Hayes  
Assistant Director  
Office of Healthcare and Insurance

cc: Kristopher D. Brown  
Dechert LLP