



DIVISION OF
CORPORATION FINANCE

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

January 14, 2020

Alexander Zwyer
Chief Executive Officer
NLS Pharmaceuticals Ltd.
Alter Postplatz 2
CH-6370 Stans, Switzerland

**Re: NLS Pharmaceuticals Ltd.
Draft Registration Statement on Form F-1
Submitted December 18, 2019
CIK No. 0001783036**

Dear Mr. Zwyer:

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.

Draft Registration Statement on Form F-1 submitted December 18, 2019

Prospectus Summary

Our Company, page 1

1. Please expand your disclosure regarding Quilience and Nolazol to briefly discuss your stage of development of these product candidates and your plans for their development in the future. Further, given your risk factor disclosure on page 10, please clarify whether you are pursuing FDA approval of one or both of the lead product candidates for use in children.
2. We note your statements throughout the prospectus that Quilience and Nolazol are "novel" pharmaceutical products and agents, yet the active molecule in these product candidates is a controlled release formulation of mazindol, which has been previously

approved in an immediate release form. Please revise the use of the term "novel" throughout the prospectus as appropriate.

Risks Associated With Our Business, page 2

3. Please include a bullet point describing the risks related to the fact that over 70% of your outstanding common stock is held by your chief executive officer and affiliates, and discuss the extent to which they will continue to exert control over you after the offering.

Implications of Being an "Emerging Growth Company", page 3

4. 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.

Risk Factors

Obtaining approval of an NDA or a Marketing Authorization Application..., page 7

5. We note your disclosure that you have not received regulatory clearance to conduct the additional clinical trials that are necessary to be able to submit an NDA to the FDA for Nolazol. Please revise your disclosure to specify the regulatory clearance needed to conduct additional trials and describe any additional steps involved in obtaining the regulatory clearance.

Risks Related to Our Intellectual Property, page 25

6. Please add a risk factor, or revise in the appropriate risk factor, to address the limitations of patents protecting the method of use as opposed to other types of patents, such as a composition of matter patent.

Use of Proceeds, page 42

7. We note that the net proceeds will be used to further develop mazindol CR for use in Quilience and Nolazol. Please revise your disclosure to specify how far in the clinical development you expect to reach with the net proceeds for each of the identified product candidates.

Business

Our Development Pipeline, page 57

8. We note that your pipeline table includes product candidates with regard to which you do not provide any information (NLS 10, NLS-13 and NLS-14) or provide limited information (NLS-2, NLS-3 and NLS-4). Please remove these product candidates from the pipeline table or tell us why you believe these product candidates are material to your business. To the extent you believe these product candidates are material, please provide disclosure regarding these product candidates, including whether you own or license the

intellectual property underlying the product candidate, the mechanism of action, any trials conducted to date and your plans for development.

Our Solution: Quilience for Narcolepsy - A Well-Suited Approach for the Disease Pathology , page 62

9. We note that in your pipeline table on page 57, it suggests that you have completed Phase 2 studies for Quilience. However, you do not provide a description of any studies conducted to date with respect to Quilience and further disclose that you have not yet submitted an IND application or CTA. Please revise your disclosure or the pipeline table to reconcile this discrepancy. To the extent you have completed any clinical trials to date, please provide a description of these trials.
10. We note your statement of belief that Quilience may qualify for the Breakthrough program "based on positive real-world evidence using the same outcome measures utilized in Phase 3 clinical trials." Please revise your disclosure to explain what this means.

Our Solution: Nolzol - The Efficacy of a CII Stimulant with Improved Safety and Tolerability, page 67

11. You make several assertions regarding the safety and efficacy of your product candidates. For example, on page 67, you state that "Nolzol has the right balance of safety and efficacy," that Nolzol demonstrated "evidence of efficacy and safety" in your Phase 2 clinical trial, and that Nolzol has "comparable efficacy, improved safety" compared to CII treatments in use today and is "a more effective treatment than the available non-stimulants." Safety and efficacy determinations are solely within the authority of the FDA (or applicable foreign regulator). Please revise or remove statements/inferences throughout your prospectus that your product candidates are safe and/or effective.

Manufacturing and Suppliers, page 74

12. We note that you rely on a single source for the production of your drug substance. Please disclose the material terms of your agreement with this supplier and file the agreement as an exhibit to the registration statement, or tell us why you do not believe this is required. See Item 601(b)(10) of Regulation S-K.

Intellectual Property, page 75

13. Please expand your disclosure to clarify the type of patent protection your applications covering mazindol CR for the treatment of ADHD and narcolepsy provide (e.g., composition of matter, method of use, etc.). Also revise to clarify the type of protection covering NLS-2, NLS-3 and NLS-4 referenced in the last sentence of the second paragraph.

Note 1: Background, page F-7

14. You disclose that as all of the companies were owned by the same shareholders, the Merger was considered to be a common controlled transaction. Please tell us the ownership interests of NLS-0 Pharma Ltd., NLS Pharma Ltd. and NLS-1 Pharma Ltd. both before and after the Merger. If any of the ownership percentages changed, please explain the appropriateness of accounting for the Merger at historical cost.

Note 2: Summary of Significant Accounting Policies
Revenue Recognition, page F-8

15. Although you indicate that you recognized revenue in accordance with ASC 606, your disclosures herein and in Note 8 appear to refer to terminology and recognition principals set forth in ASC 605. Please revise your disclosures to address your revenue recognition policies and disclosure requirements under the guidance of ASC 606. Address this comment as it relates to your Critical Accounting Policies regarding revenue recognition on page 51. Also, see our specific comment below regarding your accounting for the EF License Agreement.

Note 8: License Revenues, page F-12

16. Given the fact that you adopted the provisions of ASC 606 on January 1, 2019, please revise your disclosures to identify the performance obligations included in your EF License Agreement. Indicate the goods or services promised that are distinct and those that are combined to form a bundled performance obligation. Refer to ASC 606-10-25-14 through 22 and provide the disclosures required by ASC 606-10-50-12 and 50-13. In addition, with reference to ASC 606-10-32-28 through 35, please disclose how you determined the transaction price and the amount allocated to each performance obligation. In that regard, please address how you considered the guidance in ASC 606-10-55-50 through ASC 606-10-55-53 in accounting for the \$2.5 million payment and how you considered the other milestone payments in determining your transaction price and the extent to which such variable consideration was constrained. Refer to ASC 606-10-50-20. Please address this comment as it relates to your disclosures surrounding the accounting for your EF License Agreement on page 46.

Alexander Zwyer
NLS Pharmaceuticals Ltd.
January 14, 2020
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You may contact Michael Fay at 202-551-3812 or Jeanne Baker at 202-551-3691 if you have questions regarding comments on the financial statements and related matters. Please contact Irene Paik at 202-551-6553 or Mary Beth Breslin at 202-551-3625 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Howard Berkenblit