United States securities and exchange commission logo

May 14, 2021

Olivier Taelman
Chief Executive Officer
Nyxoah SA
Rue Edouard Belin 12
1435 Mont-Saint-Guibert, Belgium

Re: Nyxoah SA
Draft Registration Statement on Form F-1
Submitted April 16, 2021
CIK No. 0001857190

Dear Dr. Taelman:

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 April 16, 2021

Cover Page

1. When referencing the last reported sales price of your ordinary shares on Euronext Brussels, please disclose the price as converted into U.S. dollars at the most recent exchange rate.

Summary
Overview, page 1

2. We note your statement on page 2: We continue to develop a substantial body of clinical evidence to demonstrate the safety and efficacy of the Genio system and your statement on page 4 referring to the Genio system as a clinically proven solution. You also refer on

page 5 to the Genio system being a [s]afe, effective and patient-centric therapeutic option that demonstrated compelling safety and effectiveness data. Please revise these statements and all similar statements throughout your prospectus that state or imply that your product candidates are safe or effective as these determinations are solely within the authority of the FDA and comparable regulatory bodies in other jurisdictions.

3. On page 2 you state: We believe that positive results from this trial may eliminate the need for Genio system patients to undergo the DISE procedure prior to implantation of the Genio system, thereby leading to a potential indication expansion in

Europe. Please
revise to balance these statements concerning the need to undergo the DISE
procedure given on page 103 you indicated a different procedure would still be required
with the Genio system, specifically that a post-surgery sleep study will need to be
conducted to optimize the Genio system device, or advise.
4. We note your statement on page 3 that you plan to investigate and provide new
neurostimulation technologies for OSA patients through your partnership with Vanderbilt
University. Please revise to describe this partnership.
The Genio System Market Opportunity, page 3

5. Please revise page 3 to explain how you calculated an $11 billion European, Australian
and New Zealand market opportunity and $10 billion US market opportunity.
Additionally, explain how you estimated non-compliance rates. Lastly, you state that
approximately 70% of those non-compliant patients are eligible for hypoglossal nerve
stimulation based on their anatomical characteristics. Please also revise to explain in the
Summary the anatomical limitations of your device or hypoglossal nerve stimulation
devices generally.
Use of Proceeds, page 68

6. With respect to the first three bullets on page 68, please revise to specify an estimate of
how far the proceeds from this offering will allow you to reach with respect to your
development and commercialization of your Genio program in the various jurisdictions in
which you seek or have obtained regulatory approval, and the additional technologies in
your pipeline.
Capitalization, page 70

7. Please revise to provide the information required by Item 3.B of Form 20-F regarding
indebtedness.
Our Competitive
FirstName Strengths, page
LastNameOlivier 90
Taelman
Comapany
8. NameNyxoah
Please revise page SA
90 to explain the significance of receiving CE-Mark conditional
labeling for
May 14, 2021 Page 2 1.5T and 3T full-body MRI scan.
FirstName LastName
Olivier Taelman
FirstName
Nyxoah SALastNameOlivier Taelman
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May NameNyxoah SA
14, 2021
May 14,
Page 3 2021 Page 3
FirstName LastName
Clinical Results and Studies, page 103

9. Please revise to provide a brief explanation of the disclosed p-values and how p-values are
used to measure statistical significance.
10. By presenting your trial results on page 105 and then your competitor s results on page
106 your disclosure operates as a comparison. Such comparisons are not permissible
where, as is the case here, these are not head-to-head trials. Please remove the data from
page 106 showing your competitors trial results.
Business
Manufacturing and Supply, page 110

11. Please provide the sources and names of principal suppliers as

applicable. See Item
101(h)(4)(v) of Regulation S-K.
Intellectual Property, page 111

12. Please revise pages 111-112 to provide the following with respect to the Cochlear
Collaboration Agreement, the Man & Science SA license agreement and the Vanderbilt
University license agreement, as applicable:
the nature and scope of intellectual property transferred;
Each parties rights and obligations;
Duration of agreement and duration of royalty term, if any;
Termination provisions;
Up-front or execution payments received or paid;
Aggregate amounts paid or received to date under agreement;
Aggregate future potential milestone payments to be paid or received, if any;
Royalty rates or a royalty range, if any.

Please also file the Man & Science SA and the Vanderbilt University license agreements
as exhibits pursuant to Item 601 of Regulation S-K, and ensure all material contracts are
described as required by Item 10.C of Form 20-F.

13. Please revise page 111 to state the types of patents you own and the foreign jurisdictions
in which you have granted or pending patent applications.

Principal Shareholders, page 143

14. Please revise your disclosure to identify the natural person or persons who have voting
and/or investment control of the shares held by Cochlear Investments Pty Ltd, Gilde
Healthcare, TOGETHER Partnership and Resmed Inc. on page 143.

Certain Relationships and Related Party Transactions, page 145

15. Here or in the Business section, please clarify whether you have exclusive access to the
patents covered by the Man & Science SA license agreement in the Sleep Disordered
Breathing field and define the scope of this field and Shared Patents.

Description of Share Capital and Articles of Association
Articles of Association and Other Share Information, page 149

16. Please revise to disclose the exclusive forum provision of your Articles of Association,
and note any enforceability or other concerns associated therewith.

Exhibits

17. Please file your agreement with the Walloon Region.

General

18. 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 Julie Sherman at 202-551-3640 or Kevin Kuhar at 202-551-3662 if you
have questions regarding comments on the financial statements and related matters. Please
contact Margaret Schwartz at 202-551-7153 or Samuel Kluck at 202-551-3233 with any other
questions.

Sincerely,

Division of

Corporation Finance

Office of Life

Sciences

cc: John Rudy, Esq.