



DIVISION OF  
CORPORATION FINANCE

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

January 27, 2021

Dagi Ben-Noon  
Chief Executive Officer  
Inspira Technologies OXY B.H.N. Ltd  
2 Ha-Tidhar St.,  
Ra'anana, 436650  
Israel

**Re: Inspira Technologies OXY B.H.N. Ltd**  
**Draft Registration Statement on Form F-1**  
**Submitted December 29, 2020**  
**CIK No. 0001837493**

Dear Mr. Ben-Noon:

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

Prospectus Summary

Our Company, page 1

1. We note your statement here, on page 66 and on page 73 that the mortality rate for patients on MV was approximately 50% and that as a result of the COVID-19 pandemic, the mortality rate for patients on MV is estimated to have increased to 70%. Please revise your disclosure to provide the bases for these claims.
2. We note your statement on page 1 that your AXT system has the potential to reduce patients' length of stay in ICU, rehabilitation period in the hospital and re-admission rate.

We further note your disclosures on page 2 highlighting ease of use and affordability. Please balance these claims by explaining that your product candidate remains in development, has not been tested in humans, and is not cleared or approved by FDA or similar foreign regulatory bodies. To the extent that claims are supported by pre-clinical data or some other basis, please clarify.

3. Please revise the final paragraph on page 1 to clarify whether/when you developed a prototype of the AXT system. Given your disclosure concerning the development and design work that remains to be completed, please tell us whether the graphic on page 71 depicts a prototype and whether that product was used in the pre-clinical studies cited on pages 73-74.

Implications of Being an Emerging Growth Company, page 4

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.

Use of Proceeds, page 49

5. Please revise your disclosure to include the meaning of the phrase "product integration." Please also revise to include (i) whether the net proceeds of the offering will be sufficient to fund the purposes listed in this section and (ii) if a material amount of other funds is necessary, the amount necessary and sources of such other funds.

Management's Discussion and Analysis of Financial Condition and Results of Operations

Critical Accounting Policies and Estimates

Share-based compensation , page 60

6. Please revise your disclosure to provide an analysis of the uncertainties associated with the methods, assumptions and estimates underlying your accounting policy for share-based compensation to provide greater insight into the quality and variability of information regarding your financial condition and operating performance. In doing so, please
  - Clarify how the volatility rate used in your option pricing model was established. If the 50% rate disclosed on page F-44 was based on similar companies' stock volatility, please tell us the companies that formed the basis for it, and explain what makes such companies similar and comparable. Tell us about any limitations or uncertainties over that comparability. Refer to paragraph 47(a) of IFRS 2, and expand your disclosures within Note 2 of your financial statements as well, as applicable.
  - Clarify what you mean by the statement that the share price is determined according to the last known closing price of your Ordinary Shares at the grant date. Clarify your disclosure that states that your shares started trading on a stock exchange in

February 2011 given that you disclosed elsewhere in the document that you were incorporated in Israel in 2018.

7. Once you have an estimated offering price or range, please explain to us how you determined the fair value of the common stock underlying your equity issuances, and the reasons for any differences between the recent valuations of your common stock leading up to the initial public offering and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation and beneficial conversion features. Please discuss with the staff how to submit your response.

Business

Industry Overview, page 68

8. We note your statement that it is believed that millions of additional American adults suffer from COPD but have not been diagnosed and are not being treated. Please revise your disclosure to clarify the source for this statement as well as other similar statements, including, without limitation, the following ones:
  - More than half of patients are placed on mechanical ventilators within the first 24 hours of their admission to the ICU.
  - Recent data states that 18-69 hours of complete diaphragmatic inactivity associated with MV decreases cross-sectional areas of diaphragmatic fibers by more than 50% and that MV may affect the regulation of the respiratory center.
  - Total hospital stay costs for each patient admitted to ICU may reach approximately \$148,000.

Currently Available Respiratory Support Solutions and Their Limitations, page 68

9. We note your statements in Table 1 and Table 2 regarding the advantages of AXT compared to mechanical ventilation. Given the current state of development of the AXT system, please explain to us why it is appropriate for you to state that the AXT system has competitive advantages over FDA-approved treatments. Please also revise your disclosure to (i) clarify, if true, that any potential benefits of the AXT system as compared to MV have yet to be observed in human trials and (ii) discuss any detriments related to the AXT system. Please also revise Table 2 to clarify which products or treatments are being compared to the AXT system.

Market Opportunity, page 73

10. Please provide us with the sources for your claims in the second paragraph on page 73 including:
  - the prevalence of COPD is estimated to range between 7% and 19%;
  - 3 million people are estimated to be suffering from acute respiratory distress syndrome annually;
  - the U.S. Health Organization statement that the growing number of people suffering

- from respiratory problems could trigger an "economic tsunami"; and
- the hospital admission and cost numbers discussed in the paragraph.

Pre-Clinical Data and Results, page 75

- Please revise your description of Table 3 to clarify whether each row represents an individual pig or refers to the results of a pre-clinical study.

Production and Manufacturing, page 76

- Your disclosure on page 15 indicates that you are reliant on a limited number of suppliers, including sole and single-source suppliers. Please revise your disclosure in this section to discuss your manufacturing process in more detail, including any reliance on sole and single-source suppliers and the availability of alternative sources of supply.

Research and Development and Governmental Grants, page 76

- Your disclosure on page 38 and in the notes to your financial statements appears to indicate that the total amount of the grants received are "linked to the U.S. dollar and bearing interest at an annual rate of LIBOR applicable to U.S. dollar deposits." Please revise your disclosure in this section, and elsewhere in the document as appropriate, to clarify whether the total amount of the grant that must be repaid through royalties will increase until repayments begin. Please also file the grant agreement as an exhibit to your registration statement or explain to us why it is not required to be filed.

Management

Executive Compensation, page 85

- We note that you present executive compensation on an aggregate basis. However, your disclosure on page 35 indicates that the Israeli Companies Law requires you to disclose the annual compensation of your senior officers on an individual basis. Accordingly, please present the executive compensation of your directors and senior officers on an individual basis, or advise. Refer to Part I, Item 6.B. of Form 20-F (incorporated by reference into Form F-1).

Related Party Transactions

Shareholders Loans, page 105

- We note your discussions of the IPO deed among you, InSense Medical Pty Ltd. ("IML"), the Founders and Newburyport Partners Pty Ltd. We note that at the time of this agreement, based on disclosure elsewhere in the prospectus, you were named InSense Medical Ltd. We further note that IML is listed as one of your 5% shareholders on page 104. Please revise your disclosure to clarify the nature of the relationship between you and IML including whether (i) the references to IML on pages 105-106 are actually a reference to you or to a subsidiary and (ii) both you and IML have the same shareholders.

16. Please revise to explain briefly why you did not conduct the initial public offering on the Australian Securities Exchange.

Description of Share Capital, page 107

17. We note your statement that you issued 27,795,209 ordinary shares to "Inspira Technologies Limited". Please revise your disclosure to indicate whether this is a reference to the shares issued to IML and Newburyport discussed on page 106 or if your disclosure on page 107 refers to a separate issuance of shares.

Audited Financial Statements for the Years Ended December 31, 2019

Statements of Comprehensive Loss, page F-6

18. You indicate that the number of shares in your statements of comprehensive loss have been restated based on rights issuance according to subsequent event note. Please include disclosure in Notes 9.B on page F-24 and 3.B on page F-42 in quantified detail regarding the transaction you are adjusting for, to include your calculations of the weighted average number of outstanding shares used in your loss per share calculation. Please tell us why the basic EPS and diluted EPS is the same on the face of your unaudited condensed interim statements of comprehensive income on page F-36, in light of the fact that you have options outstanding at June 30, 2020, and revise your presentation as appropriate. If the options are not included in the calculation of diluted earnings per share because they are antidilutive, the amount and nature of the instruments excluded should be disclosed in Note 3.B on page F-42 in accordance with paragraph 70(c) of IAS 33. Please assure that this note presents information for the six months periods ended on June 30, 2020 and 2019. Please ask your independent auditor to revise its report on page F-3 to reference the retroactive adjustment to the number of shares disclosed in your audited financial statements.

Notes to Financial Statements

Note 2 - Significant Accounting Policies

Share Based Compensation, page F-16

19. We note your disclosure explaining that where equity instruments are granted to persons other than employees, the statement of comprehensive loss is charged with the fair value of goods and services received. We also note your disclosure in the notes to the unaudited condensed interim financial statements on page F-44 that states that "Since the service providers are not employees, the fair value at the grant date was not determined in accordance with services provided but rather in accordance with the options' fair value." Please revise to address the following:
- Reconcile the apparent inconsistencies between these disclosures.
  - Explain to us how your accounting policy for recording instruments granted to non-employees complies with IFRS 2. Specifically clarify the extent to which you were able to reliably estimate the fair value of the goods or services received in your

- response as well as in your revised disclosure.
- Please identify the method of settlement, e.g. cash or equity in your accounting policy disclosure for all of your significant share based awards. Revise your disclosures on page F-16 to clarify as applicable.

Note 3 - Critical accounting estimates and judgments, page F-20

20. Please revise to specify the convertible loan issuances you refer to in this note. Please explain, with reference to authoritative literature, how you accounted for your convertible loan issuances, including subsequent modifications, referencing the accounting principle that was used and how it was applied. Revise your critical accounting estimates section in the MD&A to provide an analysis of the uncertainties associated with the methods, assumptions and estimates underlying your accounting policy for convertible loan issuances to provide greater insight into the quality and variability of information regarding your financial condition and operating performance, or direct us to existing disclosures.

Unaudited Condensed Interim Financial Statements

Notes to the Unaudited Condensed Interim Financial Statements

Note 17 - Subsequent Events, page F-31

21. We note that on December 20, 2020 you entered into a simple agreement for future equity (SAFE) and raised \$2.6 million from this equity financing. Please explain, with reference to authoritative literature, how you accounted for the elements of this transaction.

General

22. Please revise your prospectus to identify the underwriter(s) of the offering.

You may contact Ibolya Ignat at (202) 551-3636 or Kevin Vaughn at (202) 551-3494 if you have questions regarding comments on the financial statements and related matters. Please contact Alan Campbell at (202) 551-4224 or Joe McCann at (202) 551-6262 with any other questions.

Sincerely,

Division of Corporation Finance  
Office of Life Sciences

cc: David Huberman, Esq.