

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

DIVISION OF CORPORATION FINANCE

November 19, 2021

Mark White Chief Executive Officer Nexalin Technology, Inc. 1776 Yorktown, Suite 550 Houston, TX 77056

> Re: Nexalin Technology, Inc. Amendment No. 1 to Draft Registration Statement on Form S-1 Submitted November 2, 2021 CIK No. 0001527352

Dear Mr. White:

We have reviewed your amended 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.

Amendment No. 1 to Draft Registration Statement on Form S-1 submitted November 2, 2021

# Cover Page

1. We note that you expect to conduct a material portion of your research and a portion of your operations in China through a joint venture. Please disclose this prominently on the prospectus cover page. Your disclosure should make clear whether these risks could result in a material change in your operations and/or the value of your common stock or could significantly limit or completely hinder your ability to offer or continue to offer securities to investors and cause the value of such securities to significantly decline or be worthless. Your disclosure should address how recent statements and regulatory actions by China's government, such as those related to the use of variable interest entities and data security or anti-monopoly concerns, has or may impact the company's ability to

conduct its business, accept foreign investments, or list on an U.S. or other foreign exchange. Your prospectus summary should address, but not necessarily be limited to, the risks highlighted on the prospectus cover page.

2. Provide a clear description of how cash is transferred through your organization. Describe any restrictions on foreign exchange and your ability to transfer cash between entities, across borders, and to U.S. investors. Describe any restrictions and limitations on your ability to distribute earnings from your businesses, including joint ventures, subsidiaries and/or consolidated VIEs, to the parent company and U.S. investors.

## Prospectus Summary, page 2

- 3. In your summary of risk factors, disclose the risks related to doing business in China poses to investors. In particular, describe the significant regulatory, liquidity, and enforcement risks with cross-references to the more detailed discussion of these risks in the prospectus. For example, specifically discuss risks arising from the legal system in China, including risks and uncertainties regarding the enforcement of laws and that rules and regulations in China can change quickly with little advance notice; and the risk that the Chinese government may intervene or influence your operations at any time, or may exert more control over offerings conducted overseas and/or foreign investment in Chinabased issuers, which could result in a material change in your operations and/or the value of your common stock. Acknowledge any risks that any actions by the Chinese government to exert more oversight and control over offerings that are conducted overseas and/or foreign investment in China-based issuers could significantly limit or completely hinder your ability to offer or continue to offer securities to investors and cause the value of such securities to significantly decline or be worthless.
- 4. Disclose each permission that you are required to obtain from Chinese authorities to operate and issue these securities to foreign investors. State affirmatively whether you have received all requisite permissions and whether any permissions have been denied. Please disclose the consequences to you and your investors if you inadvertently conclude that approvals are not required, or applicable laws, regulations, or interpretations change.

### Overview, page 3

- 5. We note your response to prior comment 2 and reissue in part. Please provide the basis for your statement that "[t]he stigma of expensive psychotherapy or pharmaceutical medication with side effects and dependency issues will be replaced with clinically proven, safe and cost-effective technology that is undetectable to the patient during treatment."
- 6. We note your response to prior comment 3 and reissue. Please revise the Overview section of the Summary to clarify, if true, that your device was subject to a reclassification by the FDA and that in order to receive approval for the treatment of depression, a new pre-market application is required for this indication. With respect to your insomnia and

anxiety indications, please also revise the Overview section of the Summary to clarify whether you have completed the required special control trials and the new 510(k) filing that you reference on page 14.

7. We note your response to prior comment 4 and your revised disclosure on pages 3, 34, 43, and 46 regarding your statements that "based on responses from [y]our clinical providers," the alternating current waveform "has proven to be highly effective in stimulating a positive response from the mid-brain structures;" that your alternating current waveform "is safely administered to the human brain;" and that your Gen-2 device "will generate enhanced patient response[.]" We reissue in part our prior comment. It is premature for you to suggest that all of your products, including your Gen-2 and Gen-3 devices, will be determined to be safe and effective. Please revise your characterizations of results to discuss the data, rather than drawing conclusions from the results.

### Risk Factors, page 9

- 8. To the extent that your joint venture uses or may use a variable interest entity structure to conduct China-based operations, please revise your risk factors to acknowledge that if the PRC government determines that the contractual arrangements constituting part of your VIE structure do not comply with PRC regulations, or if these regulations change or are interpreted differently in the future, your shares may decline in value or be worthless if you are unable to assert your contractual control rights over the assets of your PRC subsidiaries that may conduct all or substantially all of your operations.
- 9. Given the Chinese government's significant oversight and discretion over the conduct of your business, please revise to separately highlight the risk that the Chinese government may intervene or influence your operations at any time, which could result in a material change in your operations and/or the value of your common stock. Also, given recent statements by the Chinese government indicating an intent to exert more oversight and control over offerings that are conducted overseas and/or foreign investment in Chinabased issuers, acknowledge the risk that any such action could significantly limit or completely hinder your ability to offer or continue to offer securities to investors and cause the value of such securities to significantly decline or be worthless.
- 10. In light of recent events indicating greater oversight by the Cyberspace Administration of China over data security, particularly for companies seeking to list on a foreign exchange, please revise your disclosure to explain how this oversight impacts your business and your offering and to what extent you believe that you are compliant with the regulations or policies that have been issued by the CAC to date.
- 11. We note from the audit opinion that you have a U.S. based auditor that is registered with the PCAOB and currently subject to PCAOB inspection. Please disclose any material risks to the company and investors if it is later determined that the PCAOB is unable to inspect or investigate completely your auditor because of a position taken by an authority in a foreign jurisdiction. For example, disclose the risk that lack of inspection could cause

> trading in your securities to be prohibited under the Holding Foreign Companies Accountable Act and as a result an exchange may determine to delist your securities.

- 12. Please expand your risk factor disclosure to discuss that the United States Senate passed the Accelerating Holding Foreign Companies Accountable Act, which, if enacted, would decrease the number of non-inspection years from three years to two, thus reducing the time period before your securities may be prohibited from trading or delisted.
- 13. Please tell us your consideration of whether the PRC Scientific Data Measures presents a risk to your business that should be disclosed here. We note that you may be restricted from transferring your scientific data abroad, such as your preclinical and/or clinical studies conducted within China, or to your foreign partners in China. Please tell us which parts of your business are relevant to this consideration. Please also clarify the risk factor on page 17 to disclose whether the PRC could prevent you from seeking foreign approval and commercialization of your product candidates.

We may require substantial additional funding to meet our financial needs and to pursue our business objectives, page 10

14. We note your response to prior comment 7 and your revised disclosure on page 10 stating that the use of the net proceeds will enable you to fund your operating expenses and capital expenditure requirements through calendar year 2023. However, we were unable to locate specific disclosure that provides a basis for the statement that you expect to be cash flow positive in 2023. Please revise your disclosure to more clearly explain the basis for this statement.

Our amended and restated certificate of incorporation will provide that the Court of Chancery of the State of Delaware..., page 27

15. We note your response to prior comment 11 and your revised disclosure stating that there is uncertainty as to whether a court would enforce your exclusive forum provision and that provision may result in increased costs for investors to bring a claim. We reissue in part our prior comment. Please revise to disclose whether this provision applies to actions arising under the Exchange Act.

# Next Generations, page 48

16. We note your response to prior comment 16 and your revised disclosures regarding your hypotheses about your new advanced waveform and the current pilot study. We also note your statement that "deeper penetration also enhances patient response . . . ." We reissue in part our prior comment. Please revise this and similar statements to eliminate conclusions or predictions that your device is safe and effective as determinations of safety and efficacy are solely within the authority of the FDA. In your revised disclosure, please discuss the data, rather than drawing conclusions from the results.

### Summary of Current Clinical Trial Strategy for the Joint Venture, page 51

17. We note your response to prior comment 21 and your revised disclosure that "[c]linical providers have indicated to [you] a strong and positive response from treatment-resistence patients." We reissue in part our prior comment. Please revise statements that trial results "would further bolster your FDA approval process demonstrating both safety and efficacy," to eliminate conclusions or predictions that your product candidates are effective as determinations of efficacy are solely within the authority of the FDA.

### Regulatory Strategy, page 53

18. We note your response to prior comment 22 and your revised disclosure on page 53 related to the deadline to submit clinical testing data to the FDA. We reissue in part our prior comment. Please revise to clarify whether you are permitted to continue marketing your Gen-1 device for the treatment of anxiety and insomnia before the amended 510(k) application is approved by the FDA.

#### Intellectual Property Matrix, page 54

19. We note your response to prior comment 23 and your revised disclosure on the intellectual property matrix. Please revise further to clarify the patent expiration dates for all issued patents as well as the expected expiration dates for pending patent applications.

Board of Advisors, page 66

20. Please file the board of advisors agreements with Tucker Anderson, Leonard Osser, and Gian Domenic Trombetta as exhibits pursuant to Item 601(b)(10) of Regulation S-K or tell us why such filings are not required.

You may contact Gary Newberry at 202-551-3761 or Terence O'Brien at 202-551-3355 if you have questions regarding comments on the financial statements and related matters. Please contact Joshua Gorsky at 202-551-7836 or Jeffrey Gabor at 202-551-2544 with any other questions.

Sincerely,

Division of Corporation Finance Office of Life Sciences

cc: Martin Siegel, Esq.