



DIVISION OF  
CORPORATION FINANCE

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

October 15, 2021

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

**Re: Nexalin Technology, Inc.**  
**Draft Registration Statement on Form S-1**  
**Submitted September 17, 2021**  
**CIK No. 0001527352**

Dear Mr. White:

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 S-1 submitted September 17, 2021

Prospectus Summary

Overview, page 6

1. We note your disclosure that you provide an FDA-cleared, easy-to-administer treatment that utilizes bioelectronic medical technology to safely and successfully treat various mental health disorders. Please revise to clearly disclose the indications for use from the device clearance. Please also clarify which device version has been cleared.
2. Please revise to provide the basis for your statements that your proprietary waveform "distinguishes [y]our devices from all comparable neurostimulation technologies currently available," and 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."

3. We note your disclosure that prior to a regulatory change, your Gen-1 device was also used to treat depression. Please revise 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 to clarify whether you have completed the required special control trials and the new 510(k) filing that you reference on page 14.
4. We note your statements that you develop products "to uniquely and effectively help combat the ongoing global mental health epidemic;" that your waveform is "proven to be highly effective in stimulating a positive response from the mid-brain structures;" that your advanced waveform "is safely administered to the human brain," that your Gen-2 device "will generate enhanced patient response," and that you are able to "preserve product safety and integrity" with respect to your Gen-3 device. Although we note your disclosure that the FDA has cleared your Gen-1 device, 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 these statements throughout the prospectus to eliminate conclusions or predictions that such devices are safe and effective as determinations of safety and efficacy are solely within the authority of the FDA. You may provide a summary of the data that you used to draw these conclusions, and such discussion is more appropriate in the Business section where full and proper context can be provided.

Chinese Market, page 7

5. Please revise to describe the material steps you must complete in order to form the joint venture. Please also file the joint venture agreement as an exhibit to your registration statement pursuant to Item 601(b)(10). Alternatively, please explain to us why such disclosure is not required. Please also remove statements that treatment clearance by the China National Medical Products Administration (NMPA) for the 15 milliamps power parameters is expected in the next six months, as this statement appears to be speculative.

Risks Associated with Our Business, page 7

6. Please revise to highlight your auditor's explanatory paragraph regarding your ability to continue as a going concern.

Risk Factors

We may require substantial additional funding to meet our financial needs and to pursue our business objectives, page 13

7. We note your disclosure that you are currently not cash flow positive and do not expect to be cash flow positive until 2023. Please revise to provide the basis for your statements that you expect to be cash flow positive in 2023.

We rely on collaborations with third parties for the development of our products, page 15

8. We note your disclosure that you rely on collaborations with third parties for the development of your products. Please identify any material strategic collaboration you continue to rely on in this risk factor. In addition, to the extent you have not done so, in your Business section, please describe the material terms of the collaboration agreements you have entered into and also file the agreements as exhibits to your registration statement pursuant to Item 601(b)(10) of Regulation S-K. Alternatively, please explain to us why such disclosure is not required.

Risks Related to Doing Business in China, page 19

9. We note your risk factor disclosure that a material portion of your operations and assets are located in China. However, we also note that your principal executive offices are located in the United States and that the joint venture with Wider has not yet been completed. Please explain to us in greater detail the operations and assets of the Company that are located in China.

"We are an emerging growth company . . . ", page 29

10. On the cover page, you have indicated you have elected to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 7(a)(2)(B) of the Securities Act. On page 30, you state you have irrevocably elected not to avail yourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. Please revise these conflicting statements here and throughout the filing.

Our amended and restated certificate of incorporation will provide that the Court of Chancery of the State of Delaware and the, page 29

11. We note that your forum selection provision identifies the Court of Chancery of the State of Delaware as the exclusive forum for certain litigation, including any "derivative action," and the U.S. federal district courts as the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. Please revise to disclose whether this provision applies to actions arising under the Exchange Act. Additionally, please revise your risk factor to disclose that there is uncertainty as to

whether a court would enforce such provision and that there is also a risk that your exclusive forum provision may result in increased costs for investors to bring a claim.

Use of Proceeds, page 33

12. We note your disclosure that you intend to use the net proceeds from the offering to, among other things, fund clinical research, trials and development work for future product candidates and for working capital. Please revise your disclosure to describe how far the proceeds are expected to enable you to progress in the clinical development of your product candidates. With respect to the proceeds used for working capital, please revise to provide more meaningful and specific disclosure of the intended use of proceeds.

Management Discussion and Analysis . . .

Year Ended December 31, 2020 Compared to the Year Ended December 31, 2019, page 38

13. Your table includes two line items for stock-based compensation expense and for selling, general and administrative expense. Your financial statement classifies these two line items as selling, general and administrative expense and as a loss on impairment of right of use asset, respectively. Please revise your discussion of these expenses to be consistent with the financial statement presentation.
14. On page 6, you state that you have devoted substantially all your financial resources and efforts to research and development. Please quantify and provide a discussion of your research and development expenses as part of this discussion and disclose the amount of these expenses in your financial statements or the related footnotes or, otherwise, explain to us why such discussion and disclosure is not required. Refer to Item 303(a) of Regulation S-K.

Depression Market , page 45

15. Please revise to provide the basis for your statement that any decline in the depression medication market will indirectly accelerate the growth of the neurostimulator market and that prior to 2019, your existing Gen-1 medical device had been used to successfully treat depression in the USA.

Substance Use Disorders (Opioid Addiction) Market, page 46

16. We note your statements that your pilot study "will provide a source of validation" for your treatment approach, that "initial anecdotal research with [y]our products in the addiction treatment model is promising," that your new advanced waveform allows you to "increase the power of the device exponentially without creating any safety risks," that "deeper penetration also enhances patient response. . ." and that the new advanced waveform at 15 milliamps "has been proven to be safe and highly effective in the treatment mental illness." Please revise these 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.

Marketing and Growth Strategy, page 48

17. Please revise to clarify, if true, that the Company is currently in Phase 1 and indicate if any of the Phase 1 activities have been completed. We also note that in 2020 and 2019, the Company generated revenues from licensing and treatment fee agreements with customers and from equipment by selling additional individual nodes to customers for use with your device. Please revise to clarify if the Phase 1 pricing has been implemented and clearly describe the material terms of the licensing and treatment fee arrangements with your customers.

Summary of Current Clinical Trials in the United States, page 49

18. We note your disclosure that the endpoint of the first UCSD study will provide pilot data to validate your benefits in treating opiate addiction and that a primary endpoint of the second UCSD study is validating your treatment for veterans diagnosed with mTBI and PTSD. Please revise to clearly identify the trial endpoints in each study. Please also revise to clarify if the trials are currently still paused.
19. Please revise your statements that "providing this type of data will accelerate [y]our acceptance and approval in the regulatory and treatment community" to remove any implication that you will be successful in advancing your product candidate in a rapid or accelerated manner as such statements are speculative.
20. We note your disclosure that the UPenn pilot data demonstrated that 73% of patients that received your treatment had a 50% reduction in depression symptoms in a 5-day treatment window. Please revise to disclose the total number of patients enrolled in the study.

Summary of Current Clinical Trial Strategy for the Joint Venture, page 50

21. Please revise statements that your device has been shown in multiple trials "to be highly effective in the treatment of depression" and 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 52

22. We note your disclosure that as a result of the pandemic, the deadline for submitting clinical testing data to the FDA was extended. Please revise to disclose the new deadline. Please also 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 53

23. Please revise to clarify the patent expiration dates and expected expiration dates for pending patent applications.

Mark White  
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Page 6

Narrative to Summary Compensation Table, page 67

24. Please file the employment agreement with Mark White and David Owens as exhibits to the Registration Statement pursuant to Item 601(b)(10) of Regulation S-K. Alternatively, please explain to us why such disclosure is not required.

Issuances of Share Capital, page F-21

25. Please revise your disclosure to provide the information required under Item 701 of Regulation S-K.

General

26. Please 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 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 Deanna Virginio at 202-551-4530 or Jeffrey Gabor at 202-551-2544 with any other questions.

Sincerely,

Division of Corporation Finance  
Office of Life Sciences

cc: Martin Siegel, Esq.