

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

FORM 10-K

X ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2022

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission file number: 001-41507

**NEXALIN TECHNOLOGY, INC.**  
(Exact name of Registrant as specified in its charter)

<u>Delaware</u> (State or other jurisdiction of incorporation or organization)	<u>27-5566468</u> (I.R.S. Employer Identification No.)
<u>1776 Yorktown, Suite 550 Houston, TX</u> (Address of principal executive offices)	<u>77056</u> (Zip Code)

Registrant's telephone number, including area code: (832) 260-0222

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.001 per share	NXL	The Nasdaq Capital Market
Warrants, exercisable for one share of Common Stock	NXLIW	The Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Securities Exchange Act: NONE

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No X

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15 (d) of the Securities Exchange Act. Yes  No X

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes X No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes X No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of large accelerated filer, accelerated filer, smaller reporting company, and emerging growth company in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer	<input type="checkbox"/>	Accelerated Filer	<input type="checkbox"/>
Non-Accelerated Filer	X	Smaller Reporting Company	X
		Emerging Growth Company	X

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accountant standards provided pursuant to Section 13(a) of the Exchange Act. Yes  No X

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes  No X

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. Yes  No X

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). Yes  No X

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No X

The registrant completed its initial public offering on September 16, 2022. The registrant's common stock had an issue price of \$4.15 per share. Based upon the initial public offering price of \$4.15, the aggregate market value of the voting and non-voting common equity held by non-affiliates, as of September 16, 2022 was \$23,476,985.

As of March 22, 2023, there were 7,286,562 shares of the Registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

List hereunder the following documents if incorporated by reference and the Part of the Form 10-K (e.g., Part I, Part II, etc.) into which the document is incorporated: (1) Any annual report to security holders; (2) Any proxy or information statement; and (3) Any prospectus filed pursuant to Rule 424(b) or (e) under the Securities Act of 1933.

None

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### SPECIAL CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain information included or incorporated by reference in this document may not address historical facts and, therefore, could be interpreted to be "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including projections of financial performance; statements of plans, strategies and objectives of management for future operations; any statement concerning developments, performance or industry rankings relating to products or services; any statements regarding future economic conditions or performance; any statements of assumptions underlying any of the foregoing; and any other statements that address activities, events or developments that Nexalin technology, Inc. and its subsidiaries ("Nexalin" or the "Company" and also referred to as "we," "us" and "our") intends, expects, projects, believes or anticipates will or may occur in the future. Forward-looking statements may be characterized by terminology such as "believe," "anticipate," "expect," "should," "intend," "plan," "will," "estimates," "projects," "strategy" and similar expressions. These statements are based on assumptions and assessments made by the Company's management in light of its experience and its perception of historical trends, current conditions, expected future developments and other factors it believes to be appropriate. Any such forward-looking statements are not guarantees of future performance (financial or operating), and actual results, developments and business decisions may differ materially from those envisioned by such forward-looking statements. These forward-looking statements are subject to a number of risks and uncertainties that include but are not limited to the following: the outbreak and continued impact of the novel coronavirus ("COVID-19") and its variants in the United States and China, including the measures to reduce its spread, and its impact on the economy and demand for our services and products, are uncertain, cannot be predicted, and may precipitate or exacerbate other risks and uncertainties.

- our plans to develop and commercialize our products;
- our planned clinical trials for our products;
- the timing of the availability of data from our clinical trials;
- the timing of our selection of an initial clinical candidate from our program;
- the timing of our planned FDA related regulatory filings;
- the timing of and our ability to obtain and maintain regulatory approvals for our products;
- the clinical utility of our products and their potential advantages compared to other treatments;
- our commercialization, marketing and distribution capabilities and strategy;

- our ability to establish and maintain arrangements for the manufacture of our products;
- our ability to establish and maintain collaborations and to recognize the potential benefits of such collaborations;
- our estimates regarding the market opportunities for our products;
- our intellectual property position and the duration of our patent rights;
- our estimates regarding future expenses, capital requirements and needs for additional financing; and

the other risk factors set forth under Item 1A, Risk Factors, in this Annual Report on Form 10-K and in our other SEC filings. The forward-looking statements included herein apply only as of the date of this Annual Report on Form 10-K. The Company disclaims any duty to update such forward-looking statements, all of which are expressly qualified by the foregoing, except as may be required by law.

## PART I

### ITEM 1. BUSINESS

#### *Overview*

We design and develop innovative neurostimulation products to uniquely and effectively help combat the ongoing global mental health epidemic. We developed an easy-to-administer medical device — referred to as Generation 1 or Gen-1 — that utilizes bioelectronic medical technology to treat anxiety and insomnia, without the need for drugs or psychotherapy. Our original Gen-1 devices are cranial electrotherapy stimulation (CES) devices that emit waveform at 4 milliamps during treatment and are presently classified by the U.S. Food and Drug Administration (“FDA”) as a Class II device.

Medical professionals in the United States have utilized the Gen-1 device to administer to patients in clinical settings. While the Gen-1 device had been cleared by the FDA to treat depression, anxiety, and insomnia, three prevalent and serious diseases, because of the FDA’s December 2019 reclassification of CES devices, the Gen-1 device was reclassified as a Class II device for the treatment of anxiety and insomnia. We are required to file a new application under Section 510(k) of the Federal Food, Drug and Cosmetic Act (“510(k) Application”) to be approved by the FDA for the sales and marketing of our devices for the treatment of anxiety and insomnia. In the FDA’s December 2019 reclassification ruling, the treatment of depression with our device will require a Class III certification and require a new PMA (premarket approval) application to demonstrate safety and effectiveness.

While we continue providing services to medical professionals to support patients’ use of the Gen-1 devices which were in operation prior to December 2019, we are not making new sales or new marketing efforts of Gen-1 devices. We continue to derive revenue from devices which we sold or leased prior to the FDA’s December 2019 reclassification announcements. This revenue consists of monthly licensing fees and payments for the sale of electrodes. We have suspended marketing efforts for new sales of devices related to the Gen-1 device for treatment of anxiety and insomnia in the United States until the Nexalin regulatory team makes a decision on whether to proceed with a new 510(k) application at 4 milliamps, which determination will be based on FDA comments expected to be received in mid or late spring 2023. Our regulatory team continues to inform the FDA of the suspension of the marketing and sale of the Gen-1 products to new providers.

#### *Our Technology*

We have designed and developed a new advanced waveform technology to be emitted at 15 milliamps through new and improved medical devices referred to as Generation 2 or Gen-2 and Generation 3 or Gen-3. Gen-2 is a clinical use device with a modern enclosure to emit the new 15 milliamp advanced waveform. Gen-3 is a new patient headset that will be prescribed by licensed medical professionals in a virtual clinic setting similar to existing tele-health platforms. The Nexalin research team believes that the new 15 milliamp Gen-2 and Gen-3 devices can penetrate deeper into the brain and stimulate associated structures of mental illness, which we believe will generate enhanced patient response without any risk or unpleasant side effects. The Nexalin regulatory team has made a strategic decision to develop strategies for pilot trials in various mental health disease states. In addition, a new PMA application in the United States is in development for the treatment of depression utilizing both Gen-2 and Gen-3. The new Gen-3 device is also scheduled for additional pilot trials for anxiety and insomnia in the United States and China beginning in the late second quarter or early third quarter of 2023. Preliminary data provided by the University of California San Diego supports the safety of utilizing our 15 milliamp waveform technology. However, the determination of safety and efficacy of medical devices in the United States is subject to clearance by the FDA.

Additionally, we are currently designing clinical trial strategies for the use of Gen-3 for the treatment of substance use disorders including opiate, cocaine, and alcohol abuse. Recently the Gen-2 device was tested in pilot trials in China for the treatment of Alzheimer’s disease, and dementia. Continued pilot testing for Alzheimer’s and dementia is planned in China in 2023.

In part due to increased incidence attributed to the devastating impacts of the COVID-19 pandemic, mental health and cognitive disorders are widespread across the globe and causing substantial health, social and economic losses, and hardships accordingly. Our focus is on the continued development of our innovative bioelectronic medical technologies and rapid regulatory approval.

Our products are non-invasive, safe, undetectable to the human body and can provide relief to those afflicted with mental health issues without adverse side effects. We have a proprietary design that eliminates voltage while stabilizing currents, electromagnetic fields, and various frequencies — referred to collectively as waveform - particularly our proprietary, 15 milliamp patented symmetrical waveform. Our devices generate a high frequency carrier wave that is charge balanced is applied to the brain with an array of electrodes on the forehead and behind each ear at the mastoid. The features of this proprietary waveform and the array of electrodes allows the application of the waveform to the entire brain rather than a small, targeted area of the brain. To ensure deeper penetration in the brain, we have eliminated the voltage from the waveform which allows the increase of the power from < 4 mAmps to 15 mAmps, more than a 400% increase without incurring any patient discomfort, risk, or adverse side effects. By increasing the power, our waveform can penetrate deeper into the brain and stimulate deep mid-brain structures associated with mental illness. Our research and clinical teams believe that a more powerful waveform will create a stronger response in the brain. A stronger response creates a higher level of efficacy. This entire proprietary technique allows Nexalin to provide a safe and comfortable treatment that is more powerful than any stimulation device in the market. Current pilot study protocols and randomized clinical trials have been designed and submitted to the FDA to provide feedback on final reports and data sets for the purpose of safety and efficacy evaluations in the future. Determinations of the safety and efficacy of our devices are solely within the authority of the FDA.

Currently, the waveform that comprises the basis of Gen-2 and new Gen-3 headset devices has been tested in research settings to develop safety data that has been submitted for review by the FDA for safety evaluation and eventual marketing in the United States. Determinations of the safety and efficacy of our devices in the United States are solely within the authority of the FDA.

We recognize that an additional barrier to treatment in today's mental health treatment landscape — beyond the concerns about safety, efficacy and side-effects that have been associated with conventional mental health treatments such as ECT (shock therapy), drugs and psychotherapy is stigma. Industry reports and feedback indicate that many patients that struggle with mood disorders have the stigma of embarrassment associated with psychiatrists and psychotherapy (e.g., counselling with a therapist). Additional stigmas and other issues are associated with the side effects of medication prescribed by psychiatrists. When we researched the current pharmaceuticals model, public information highlighted the many side effects associated with these medications. Frequently, patients would stop taking the medication because of the uncomfortable side effects. Additional public information mentions dependency and withdrawal issues associated with medication for psychiatric disorders.

To address the embarrassment stigma, we are developing a new virtual clinic. After diagnosis, the physician can prescribe the Nexalin Gen-3 headset to the patient for treatment. Next, the Gen-3 device will be shipped to the patient's home. After patient receives the device, they will pair the headset device with an app in the patient's smart phone. The app will communicate with the Nexalin cloud servers to authorize the device for treatment according to the protocol designed by the physician. The physician will monitor treatment compliance and other health related issues in a private physician dashboard that connects through the Nexalin app and cloud servers. We believe that to preserve product safety and integrity for home use, the headset device will require physician oversight that includes a prescription for use with a monthly authorization provided by the physician after a monthly virtual visit. All appointments will be in a virtual setting to provide privacy and convenience for the physician and patient. The Nexalin virtual clinic will be provided in a proprietary virtual platform which is currently in the design stage.

Our China Gen-2 15 milliamp device was recently approved in China by the NMPA for the treatment of insomnia and depression in China. This device and all other clinical devices will include a single use electrode for long term revenue streams.

Our USA Gen-2 device will have a fresh and modern appearance that meets the technology standards of the digital tech world of 2023. Early adopters of the Gen-1 device will be able to access additional firmware upgrades which are planned to enhance the previously purchased devices to the new 15-milliamp waveform.

Our Gen-2 device is expected to be equipped with RFID technology that exchanges electrode usage data with a reader in the main device. The purpose of RFID is to track and maintain control of the proprietary single use electrode. Our electrode chip will be programmed to exchange data with the device and allow activation for a single treatment with a new electrode only. We anticipate that this will ensure a recurring revenue stream on the device and protects against any generic knockoffs designed to avoid treatment costs. This upgrade in technology also ensures the proprietary nature of the electrodes that support treatment outcomes are sustained.

### *Potential Joint Venture; China Related Activities*

In September 2018, we entered into an agreement with Wider Come Limited, a company formed under the laws of the People's Republic of China ("Wider"), pursuant to which we and Wider have agreed to investigate the formation of a joint venture entity to be domiciled in Hong Kong (the "potential Joint Venture") to conduct additional clinical research and implement a business distribution plan for our devices in China, Macau, Hong Kong, and Taiwan. We do not have any existing operations in China and will not in the future. We do have current distribution in China through Wider, our potential Joint Venture partner. As of the date of this Annual Report on Form 10-K, (i) our operations are carried on outside of China; and (ii) the potential Joint Venture does not maintain any variable interest entity structure or operate any data center in China. However, because of the intended formation of the potential Joint Venture, we may become subject to laws of The People's Republic of China (PRC or China) relating to, among other topics, data security and restrictions over foreign investments. Further, as a result of the complexity and vagaries of the legal system in the PRC and recent statements and regulatory actions by the PRC government relating to data security, our ability to operate the potential Joint Venture may be adversely affected or subject to change and adversely impact our ability to offer or continue to offer securities to investors, with the result that our securities may significantly decline or be worthless. There can be no assurance that regulators in China will not take a contrary view or will not subsequently require us to undergo the approval procedures and subject us to penalties for non-compliance.

In March 2022, we entered into a second supplement to the Joint Venture agreement with Wider whereby the parties confirmed that the potential Joint Venture had not yet been established and is subject to further review and analysis of regulatory issues in China and the United States. Pursuant to the second supplement, the parties agreed to use their commercial efforts to complete documentation by September 30, 2022. In light of general economic conditions in China and the United States, the continued impact of regulatory issues within China and the United States and trade and political issues between the two countries, the parties determined to further extend the time frame to complete establishment of the joint venture to September 30, 2023 and entered into a Supplement 3 to the potential Joint Venture Agreement to memorialize such extension. The parties intend to continue to work together to complete the establishment prior to such extended time. Further, the parties agreed that all references within the Joint Venture agreements to funding and formation were amended from December 21, 2018 to be September 30, 2023. We anticipate that the Joint Venture will be formed by the third quarter of 2023. However, that will be dependent on the situation at that time.

When and if the Joint Venture is formed and Wider completes sales of our devices in China on behalf of the potential Joint Venture, we believe that there are no regulatory or other restrictions that would restrict either (i) the transfer from China of any proceeds resulting from such sales by Wider to the potential Joint Venture in Hong Kong, other than standard compliance with China's State Administration of Foreign Exchange ("SAFE") policies and approval process, or (ii) our receipt of our share of such proceeds from Hong Kong to us in the United States, which is not subject to SAFE's policies and approval process. The Company does not currently believe any of the Company's scientific data resulting from activities in China by the potential Joint Venture would fall within the Measures for the Management of Scientific Data promulgated by the General Office of the PRC State Council. In the event any existing or new laws or regulations or detailed implementations and interpretations are modified or promulgated, we and the potential Joint Venture will take all actions to remain in compliance with any such laws or regulations or detailed implementations and interpretations thereof. Neither we nor our potential Joint Venture Partner can at this point speak to any future changes in rules, regulations or the commercial and potentials situation that lies ahead which could affect the formation of the Joint Venture.

In September of 2021, the China National Medical Products Administration (NMPA), the equivalent of the United States Food and Drug Administration (FDA), approved the Gen-2 device for marketing and sale in China for the treatment of insomnia and depression. These treatment indications and clearances from the NMPA have allowed Wider to market and sell the Gen-2 device in China for the treatment of insomnia and depression.

### *Regulatory Background and Matters Related to our Business*

#### **United States**

Medical devices commercially distributed in the United States require either FDA clearance of a 510(k) premarket notification submission, granting of a de novo request or Premarket Approval (PMA), unless an exemption exists. Under the FDCA, as administered by the FDA, medical devices are classified into one of three classes — Class I, Class II or Class III — depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. Regulatory control increases from Class I to Class III. Prior to December 20, 2019, in the United States, all cranial electrical stimulation (CES) technology was classified as a Class III medical device (high-risk).

Class II devices are moderate risk devices and are subject to the FDA's general controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. Such special controls can include performance standards, post-market surveillance, patient registries and FDA guidance documents. Most manufacturers of Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute

the device.

Class III devices are deemed the highest risk devices by the FDA and generally include life-sustaining, life-supporting or some implantable devices or devices that have a new intended use or use advanced technology that is not substantially equivalent to that of a legally marketed device. Class III devices require a PMA. For a device that is Class III by default (because it is a novel device that was not previously classified and has no predicate), the manufacturer may request that the FDA reclassify the device into Class II or Class I via a de novo request.

To obtain 510(k) clearance, a premarket notification submission must be submitted to the FDA demonstrating that the proposed device is substantially equivalent to a predicate device. A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I (e.g., via the de novo classification process), or a device that was previously cleared through the 510(k) process. The FDA's 510(k) review process usually takes from three to six months but can take longer.

After a device receives 510(k) marketing clearance, any modification that could significantly affect its safety or effectiveness or that would constitute a major change or modification in its intended use, will require a new 510(k) marketing clearance or, depending on the modification, a de novo request or PMA approval. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k), de novo, or a PMA in the first instance. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until FDA has cleared or approved a 510(k), de novo or PMA for the modification.

The PMA process is more demanding than the 510(k) premarket notification process. In a PMA, the manufacturer must demonstrate that the device is safe and effective, and the PMA must be supported by extensive data, including data from preclinical studies and human clinical trials. The PMA must also contain, among other things, a full description of the device and its components, a full description of the methods, facilities and controls used for manufacturing and proposed labelling. Following receipt of a PMA submission, the FDA determines whether the application is sufficiently complete to permit a substantive review. If the FDA accepts the application for review, it has 180 days under the FDCA to complete its review of a PMA, although in practice, the FDA's review often takes significantly longer, and can take up to several years.

On December 20, 2019, the FDA issued new rulings related to CES devices for the treatment of anxiety, depression, and insomnia. As a result of these rulings, depression treatment with CES devices remained a Class III medical device and will require a full PMA that provides definitive clinical trial evidence of effectiveness and safety. A PMA is the most extensive application and process at the FDA. All CES manufacturers had one year to prepare and file intentions for the depression treatment with a PMA. CES devices that treat anxiety and insomnia were reclassified as Class II devices and required a new application in the form of a special control trial, a summary version of a PMA, requiring safety data and mild efficacy response. All CES manufacturers had one year to complete special control trials for anxiety and insomnia. We are presently analyzing our previous 510(k) Application for such treatment of anxiety and insomnia in accordance with the FDA reclassification ruling in December 2019. Our intent is to move forward with our new 15 milliamp waveform given its success in the China studies. We have also completed 2 prototypes of a Nexalin headset which can be used at home or in a clinical setting. The new headset will utilize the new 15 milliamp waveform. Final prototypes and design for manufacturing is expected in the third quarter of 2023.

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Due to the COVID-19 pandemic, special control trials according to the December 2019 ruling were delayed. In January 2023, we filed a new 510k pre-sub with the FDA for treatment of anxiety and insomnia with the new 15 milliamp Gen-3. Responses from the FDA are expected in the second or third quarter of 2023.

After comments from the FDA on the January 2023 pre-sub, we will begin pilot and pivotal trials for anxiety and insomnia which will take an estimated 9-18 months to complete patient recruitment and data collection. After data sets are complete and statisticians have reviewed and created a reporting matrix, members of the executive team will prepare final reports for submission to the FDA.

We have made a strategic decision to file a new PMA for the treatment of depression with the Gen-2 and Gen-3 devices that administer the new advanced Nexalin waveform at 15 milliamps. The Gen-1 device was previously cleared by the FDA at 4 milliamps and the re-classification does not prevent us from servicing previously sold or leased devices. Providers may continue to use these devices for treatment purposes. Servicing consists of warranty coverage, electrode sales, and patient cable replacement. This servicing is included in the monthly lease payment. We continue to derive revenue from devices which we sold or leased prior to the FDA's December 2019 reclassification announcements. This revenue consists of monthly license fees and payment for the sale of electrodes to clinical providers of our technology. As we are in the process of evaluating our new Gen-2 15 milliamp waveform for our technology, a strategic decision was made to not pursue a PMA for the treatment of depression on our existing Gen-1 device. Strategy development has begun for a full PMA for the treatment of depression for our next generation Gen-2 and Gen-3 devices.

## China

The NMPA is the governmental authority principally responsible for the supervision and administration of medical devices in the PRC. Medical devices in the PRC (including manufacturing, marketing, and sale) are subject to a mandatory filing/registration regime regulated by the NMPA. The exact filing pathways are mainly determined by the classification of such devices — like the United States, a three-class classification system, from Class I (lowest risk) to Class III (highest risk). Local testing and clinical trials are generally required for Class II and Class III devices. Some imported devices may need to be registered with a higher-level government authority than domestic devices.

As determined by the NMPA the three classes for devices are:

Class I — Medical devices for which routine administration can ensure safety for users and the effectiveness of the device.

Class II — Medical devices that can only be safe and effective with further control in addition to routine administration.

Class III — Medical devices that are implanted into the patient's body, pose a threat to the patient's health, or provide sustenance or life support.

All medical devices must be registered with the NMPA. An overseas device company must submit product samples to test with the NMPA. In addition, all included product information, packaging, and labels, and related material need to be translated into simplified Chinese. For a Class I device, simple product filing to NMPA are required. However, for Class II and Class III medical devices, the manufacturing company must meet all the requirements in the latest regulation, guidelines, and standards.

The NMPA approved the new Gen-2 15 milliamp device for the treatment of insomnia and depression. These treatment indications and clearances from the NMPA have allowed us to market and sell the Gen-2 device in China. Wider will be responsible for obtaining future NMPA registrations and approvals related to the marketing and sales of our devices in China.

Recent statements and regulatory actions by the Chinese government have targeted those companies whose operations involve cross-border data security or anti-monopoly concerns. Regarding data security, China has promulgated several important laws recently. Among them, on June 10, 2021, China promulgated the PRC Data Security Law ("DSL"), which became effective on September 1, 2021. The legislative intent for this law mainly includes regulating data processing activities, ensuring data security, promoting data development and utilization, protecting the data related legitimate rights and

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interests of individuals and organizations, and safeguarding national sovereignty, security and development interests. Article 36 provides that any Chinese entity that provides the data to foreign judicial or law enforcement agencies (regardless of whether directly or through a foreign entity) without approval from the Chinese authority would likely be deemed to be in violation of DSL. In addition, pursuant to Article 2 of Measures for Cybersecurity Reviews, the procurement of any network product or service by an operator of critical information infrastructure that affects or may affect national security shall be subjected to a cybersecurity review under the Measures. Pursuant to Article 35 of Cybersecurity Law of the People's Republic of China, where "critical information infrastructure operators" purchase network products and services, which may influence national security, the operators are required to be subjected to a cybersecurity review. We do not operate any critical information infrastructure. As a result, we do not believe that these new legal requirements in China are applicable to us, including sales made to date by Wider as a distributor. However, the exact scope of the term "critical information infrastructure operator" remains unclear, so there can be no assurance that the potential Joint Venture when formed will not be subjected to critical information infrastructure operator review in the future. Furthermore, in the event that the potential Joint Venture becomes an operator of critical information infrastructure in the future it may be subjected to the above-described regulation.

With regard to anti-monopoly concerns, Article 3 of Anti-Monopoly Law of the People's Republic of China prohibits "monopolistic practices," which include: a) the conclusion of monopoly agreements between operators; b) the abuse of dominant market position by operators; c) concentration of undertakings which has or may have the effect of eliminating or restricting market competition. Also, according to Article 19, the operator(s) will be assumed to have a dominant market position if it has following situation: a) an operator has 50% or higher market share in a relevant market; b) two operators have 66% or higher market share in a relevant market; c) three operators have 75% or higher market share in a relevant market. We believe that we have not conducted any monopolistic practices in China, and that recent statements and regulatory actions by the Chinese government do not impact our ability to conduct business, accept foreign investments, or list on a U.S. or other foreign stock exchange. However, there can be no assurance that regulators in China will not promulgate new laws and regulations or adopt new series of interpretations or regulatory actions which may require the potential Joint Venture to meet new requirements on the issues mentioned above.

Currently, these statements and regulatory actions of China authorities have had no impact on our daily business operation, including the sales and marketing efforts made to date of our Gen-2 devices in China through Wider. We do not believe that these statements and regulatory actions will have any impact on the potential Joint Venture when it is formed. Further, we are a United States' company with no physical presence in China, and we do not believe that the formation of the potential Joint Venture in Hong Kong and any resultant exposure to China regulatory actions will adversely impact our ability to accept foreign investments or list our securities on a United States or other foreign exchange. However, since these statements and regulatory actions from China authorities are relatively recent, it is highly uncertain how soon legislative or administrative regulation making bodies will respond and what existing or new laws or regulations or detailed implementations and interpretations will be modified or promulgated, if any, and the potential impact such modified or new laws and regulations will have on our daily business operation, the ability to accept foreign investments and list our securities on a United States or other foreign exchange. In the event any existing or new laws or regulations or detailed implementations and interpretations are modified or promulgated, we and the potential Joint Venture will take any and all actions to remain in compliance with any such laws or regulations or detailed implementations and interpretations thereof. See "Risk Factors — Risks Related to Doing Business in China."

Following the formation of the potential Joint Venture, we intend to conduct a portion of our clinical research and implement a business distribution plan for our devices in China and elsewhere through the potential Joint Venture, which we believe confers clinical, commercial, and regulatory advantages, but may subject us to significant regulatory, liquidity, and enforcement risks. Although we do not intend to have any physical presence in China, Hong Kong, Macau and Taiwan, the potential Joint Venture agreements between us and Wider contemplate that the potential Joint Venture will have a physical presence for the potential Joint Venture in Hong Kong. Wider, as a China formed entity with its physical presence in China may be subject to regulatory actions and prohibitions from China regulatory entities and required to obtain certain approvals.

The PRC legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions under the civil law system may be cited for reference but have limited precedential value. Uncertainties in the interpretation and enforcement of Chinese laws and regulations could limit the legal protections available to us.

## *Market and Industry Background*

### **General**

Historically, pharmaceutical solutions have been the first line of treatment for those who suffer from anxiety, insomnia, depression, and other mental health disorders. Beginning in 1950, for patients that were not responding to medication, ECT, also called "shock therapy," became available. Over time, researchers began to look at alternative ways to inject electricity into the human brain. One such method was via implantable neurostimulators that required invasive surgery procedures associated with high cost and high risk. Implantable devices became the potential solution for those who would not take or could no longer take pharmaceuticals. The interest in electricity continued with the creation of small handheld devices powered by a direct current (DC) battery that the consumer could buy without any medical supervision. Clinical versions of DC stimulators, known as transcranial direct current stimulation (tDCS), were developed by researchers; many of these devices are still in research settings without industry support.

In 1992, a new neurostimulation technique emerged called trans-cranial magnetic stimulation (TMS). This technique evolved into repetitive trans-cranial magnetic stimulation (rTMS), which utilized repetitive magnetic pulse energy to stimulate the brain of patients struggling with depression. The American pharmaceutical industry embraced and funded this technology. The FDA cleared rTMS only for patients who had failed to respond to anti-depressants. Side effects, high cost and moderate efficacy continue to burden this technology sector.

Both insurance companies and healthcare providers are looking for alternative ways to decrease costs while still providing safe and effective treatments.

We believe that our new marketing and growth strategy in combination with our advanced 15 milliamp waveform, technological upgrades and the development of a modern headset monitored with our IT management platform, will position us for the opportunity to disrupt the traditional mental health treatment model. Our mission is to remove the stigma of expensive psychotherapy or pharmaceuticals with the attendant side effects and dependency issues and replace it with clinically proven and cost-effective technology that is easily accessible in the privacy of the patient's home and monitored by licensed healthcare providers.

### **Anxiety Market**

Anxiety disorders are considered the most prevalent of psychiatric disorders. Anxiety disorders include generalized anxiety disorder, social anxiety disorder, panic disorder, obsessive-compulsive disorder, post-traumatic stress disorder (PTSD) and phobias.

### **Insomnia Market**

Insomnia is a common sleep disorder considered to be responsible for at least \$63 billion in direct and indirect healthcare costs each year, according to the Harvard American Insomnia Study. A frightening number of insomnia cases are undiagnosed and untreated, even as the condition becomes a mounting financial burden on America's employers and the healthcare system. Data surrounding sleep disorders demonstrate that insomnia is a growing problem that shows no signs of slowing down. Current market conditions present an opportunity to introduce a technology that provides a safe, effective and drug-free alternative for those suffering from insomnia. We believe we have the ability to decrease the number of potentially addictive insomnia prescriptions needed by patients and offer physicians a non-pharmaceutical option to provide their patients. Additionally, we are developing a solution for home-based treatment for chronic insomnia and to improve sleep hygiene for its user.

### **Depression Market**

Depression continues to be the leading cause of medical disability around the world. Poor efficacy, risk and adverse side effects of current anti-depressants are driving the preference for non-pharmacological therapies, which will limit growth for the pharmaceutical sector of the depression treatment market. This limitation will enhance the research and development of novel therapies that treat depression safely and effectively without adverse side effects. Historically, according to the CDC, only one-third of people with severe depression have taken anti-depressants.

Any decline in the depression medication market should indirectly accelerate the growth of the neurostimulator market. Management believes that, based on the market data and current trends, the depression market — like the anxiety and insomnia market — creates enormous potential for our products.

Prior to December 2019, our Gen-1 device was considered a Class III device. Treatment of depression in the United States is limited to Class III devices only. Prior to 2019, our existing Gen-1 4 milliamp medical device had been used to successfully treat depression in the U.S. The Gen-2 15 milliamp version of our device when introduced into the United States will be subject to approximately eighteen months of clinical study before our PMA application for depression will be accepted. Assuming we will be able to obtain successful classification from the FDA, we expect to market our device in the United States as a treatment for depression.

### **Substance Use Disorders (Opioid Addiction) Market**

According to the National Institute on Drug Abuse (NIDA,) substance use, and substance use disorders cost the United States more than \$740 billion a year in healthcare, crime and lost productivity costs; but dollars barely capture the devastating human cost of addiction to individuals, families and communities. According to the National Survey on Drug Use and Health, 19.7 million adults in the United States suffered from a substance use disorder in 2017.

The current success rate of the best drug and alcohol rehabilitation facilities is minimal. We believe that this represents a significant market opportunity for our company. The disease of addiction is brain-based in its nature. Currently brain-based treatments for the disease are only available to patients who can afford long-term expensive boutique treatment centers. We intend to demonstrate that a brain-based approach to addiction treatment will enhance a patient's success at long-term recovery. Our hypothesis is that the current pilot study design at the University California San Diego (see below) will provide a source of validation for this treatment modality in addiction treatment.

### **Chronic Pain Market**

Originally, our waveform was designed as an electro-analgesic for pain. This refers to the ability to electrically interrupt the pain signalling process in the brain. By interrupting the pain signalling process in the brain, our products can reduce symptoms and discomfort associated with chronic pain. By reducing the symptoms and discomfort associated with chronic pain, physicians can reduce medications and avoid dependency issues related to opiate-based medications.

According to Research and Markets, the global chronic pain treatment market is predicted to progress at a CAGR of 6.5% from 2020 to 2030 and generate revenue of \$151.7 billion in 2030.

Currently, we own an electrostimulation patent for a device that will apply electrodes to the brain, spine, and the place of injury. The placement of these electrodes in conjunction with our various waveforms creates an opportunity for us to treat chronic pain without medication. The Nexalin executive team is preparing strategies to develop a prototype of our existing patented design and introduce it into clinical trials for the treatment of chronic pain. In previous pilot studies, our existing Gen-1 product reduced pain in patients suffering from injuries originating in industrial accidents. However, we plan to use the new advanced waveform emitted at 15 milliamps into the new prototype pain device for new clinical trials for the treatment of chronic pain.

### **Alzheimer's Disease and Dementia Market**

Alzheimer's disease is a degenerative brain disease and the most common form of dementia. Dementia is not a specific disease, but rather an overall term that describes a group of symptoms. According to the WHO, there are around 50 million people living with Alzheimer's disease and other dementias worldwide.

According to Reports and Data, the global Alzheimer's therapeutics market is projected to reach \$13.57 billion by 2027 from \$7.42 billion in 2019 with a substantial compound annual growth rate (CAGR) of 9.2% through the forecast period.

We believe our products could be leveraged to extend the quality of life for millions of people who are diagnosed with Alzheimer's disease.

### *Marketing and Sales Efforts*

We believe that our marketing and sales plan provides a long-term scalable business model. Our team is preparing the foundation and marketing assets necessary to launch the new virtual clinic model that will complement the traditional clinic model. Our sales model is to place more than 1,000 Gen-2 and Gen-3 devices on the global stage. The momentum and branding strategies of Nexalin providers will be leveraged to enhance the launch of a global sales plan. The Gen-2 device at 15 milliamps supported by the Gen-3 outpatient headset and our virtual digital management platform is intended to disrupt the current mental healthcare model. The Gen-2 and Gen-3 device at 15 milliamps will offer patients a cost effective and efficient treatment model for day-to-day mental health challenges. We believe those devices, with their advanced waveform, can treat existing mental health disorders associated with anxiety and insomnia. Additionally, new strategies are in research and development for FDA treatment indications of depression, substance use disorder, opioid addiction, alcoholism and chronic pain. Additional research and treatment efficacy are being investigated for the Alzheimer's community for patient care and management.

Our plan is designed to triangulate and stimulate the physician, consumer, and manufacturer relationship. Trends in healthcare indicate consumers are involved in treatment decisions that concern their mental health. Because of the advancement in healthcare technologies, home-based care with medical supervision provides patients with a cost-effective and efficient treatment option. Home-based care also avoids the stigma associated with treatment for mental health disorders. In our current sales plan, we intend to launch with a physician provider in each state. These physicians will lead the Nexalin campaign in each state as that states primary provider. These preferred state providers will begin with the virtual clinic. Our marketing team will drive consumers with quality-of-life struggles related to mental health issues into the virtual clinic and then to the provider in the consumer's state of residence. These initial state physicians providing mental health services in the virtual clinic, will also have ability to offer treatment in their clinic. The in-clinic model will use the Gen-2 clinical device while the virtual clinic will use the Gen-3 headset. This initial launch plan with state providers will develop and support multiple marketing verticals to drive the Nexalin brand and treatment as an alternative to medications and psychotherapy. We will leverage this physician / patient community to establish a national network of physicians that offer mental health evaluations and the Nexalin treatment in either a clinical setting or in the privacy of the patient home with medical supervision through the future Nexalin app.

Most, if not all, patients treated in the Nexalin virtual clinic would be part of a digital community that supports brand awareness and the sharing of anonymous treatment outcomes in a social media setting. The Patient Activation Program will include a robust data gathering system on providers and patients (opt-in) that enhances our marketing strategies.

### *Insurance Reimbursement for Our Products*

In January 2020, the Centers for Medicare & Medicaid Services (CMS) in conjunction with the *Durable Medical Equipment for Medicare Administrative Contractors* issued a code for Cranial Electrotherapy Stimulators (CES). CMS issues codes that are used by medical practitioners to obtain Medicare, Medicaid and private insurance reimbursement. The issuance of this code is the first time that a reimbursement code from CMS has been designated specifically for CES. The code does not guarantee reimbursement and is considered at this time, experimental. The Nexalin consulting team plans to continue preparing clinical data and durability data to pursue long term clinical reimbursement.

Reimbursement strategies for this type of technology are complex and vary from one diagnosis to another. We utilize an RFID system that will track doses delivered. This will simplify comparing our devices to pharmaceutical interventions. Beginning in 2023, a complete reimbursement assessment is being conducted and evaluated to develop a strategy to acquire reimbursement. We will employ a two-prong approach for eventual reimbursement. The first prong will evaluate the clinic-based product offered by physicians. The second prong will focus on tracking usage and response from the outpatient headset model that is tracked through the virtual platform. Frequently therapies that are used in the home are not classified as durable medical equipment and will fall into a reimbursement gap without coverage. We intend to work to successfully achieve a Level 2 code under the healthcare common procedure coding system. We will work to seek reimbursement for conditions in sequence with the home based and the clinic-based unit that will maximize value of treatment from a financial standpoint as well as monitoring the response by the patient community.

### *Research*

Research is the fundamental core of any pharmaceutical or medical device company. Although small trials, with limited patients, can show promise for a treatment, they are generally not acceptable to the FDA for product approval. To commercialize a product for widespread use, multiple large-scale trials are required to demonstrate both efficacy and safety. In the past two decades, the cost of conducting such trials has more than doubled, with many small start-up companies unable to raise the necessary capital to complete these vital projects. The increase in cost reflects several variables which are required for successful clinical trial completion.

The various costs can include patient recruitment and retention expenses, physician, and nurse expenses, as well as the expenses of other healthcare providers. Various regulations, each more complex than the next, also have added significant cost to the process. Data collection, as well as data analysis, is also a significant portion of the study cost. Additionally, almost all studies are conducted through either a large university, with its underlying overhead for administrative costs and institutional review board approval, or through a contract research organization, which also adds significant overhead costs in addition to the hard cost of the study itself. Latest estimates for the cost per patient for an average trial is approximately \$41,000.

In 2019, we began a research partnership with the University California San Diego (UCSD). Prior to the pandemic, two pilot clinical studies were undertaken with UCSD, however, these trials were paused due to the shutdown of college campuses in California. In the summer of 2022, new contract negotiations began to explore strategies for PTSD and mild traumatic brain injury (mTBI). Timelines, contracts, study design and research strategies are in progress and are waiting for new pilot data sets.

Currently, a pilot trial at UCSD is focused on veterans suffering from mild traumatic brain injury (mTBI) and is funded by the United States Department of Defense. One of the primary symptoms associated with mTBI is PTSD (post-traumatic stress disorder). The primary endpoint associated with this study is the assessment and reduction of post-concussion symptoms associated with PTSD. A secondary endpoint for the study will be improvement in Magnetoencephalography (MEG) slow-wave abnormalities.

In addition to UCSD, we are developing strategies to initiate further trials to address new FDA guidelines. These new strategies and pivotal trials will support new 510(k)s for anxiety and insomnia at 15 milliamps. These trials are in addition to the special control trials required by the FDA. Final trial designs are due to be executed after recommendations are reviewed from the FDA pre-sub meetings projected to take place in Q2 2023. Other areas of research that will be designed and funded relate to the treatment of substance use disorders, Alzheimer's disease, and dementia.

Additional research in China is being performed with the goal of publishing the findings in a peer reviewed journal. All research will be controlled by our team, with all trial designs requiring written final approval by our Chief Medical Officer. Clinical updates will be required every 30-days. Frequent in-person WeChat meetings will also be performed to ensure the integrity of the research efforts.

In addition to clinical trial work in China and current studies in the United States required by the FDA, an additional study is planned with the 15 milliamp Gen-2 and Gen-3 devices to evaluate a large cohort of patients with depression. This trial will include a double-blind study design with active and sham groups. Patient selection screening will evaluate 200-250 subjects to acquire the number of patients needed for a successful trial. Each patient, upon enrollment, will be evaluated extensively prior to initiation of therapy. Patients will be treated a minimum of 20 separate times, with pre- and post-test screening. Moreover, upon completion of therapy, post-test examination will be performed not only immediately thereafter but also over the course of one to three months to establish not only efficacy but durability of the treatment. The results of this study will provide the basis of the PMA with the FDA for the treatment of Depression.

At the start of 2021, an Alzheimer's specific clinical trial was underway in China: "Transcranial alternating current stimulation for patients with mild Alzheimer's disease." Extensive cognitive pre- and post-evaluations are being performed at the beginning and conclusion of the study, with less rigorous evaluations before and after each therapy session. Because of issues related to Covid-19 in China, this trial was paused. Additionally, results of this trial will dictate additional testing strategies to determine specific treatment protocols for complex Alzheimer's and dementia patients.

A final area of study includes the evaluation of chemical changes within the brain following transcranial stimulation. Chemicals, which are naturally formed in the brain, control many of our moods and thoughts, modulating feelings of pain, depression and generalized mood. These substances also drive cravings in substance use disorders. One of the specific areas of research is to validate changes of serotonin levels in the brain. Serotonin is a "feel good" chemical which has also been associated with learning. Other chemicals, such as dopamine, act in a reward center mechanism. Additionally, certain other neurons require specific chemicals to either fire or be inhibited from firing. These areas can be explored with specific radioactive markers in the brain for evaluation with PET MRI scans.

### *Virtual Clinic Digital Management Platform*

We expect to capitalize on the post pandemic digital health model. Our team began researching IT digital development firms at the beginning of the pandemic. We have now completed our research and bidding process and have begun contract negotiations with a leading IT design team to begin work on an advanced, proprietary IT management platform that will eventually manage all aspects of the Nexalin virtual clinic model. The vision is to implement a virtual clinic model that will enable providers and clinics to integrate remote outpatients into an overall treatment process. Our IT platform goes well beyond telehealth and is designed to support all aspects of the treatment model in conjunction with various data sets to support marketing, data collection and patient monitoring. Our digital management platform will manage the entire clinical and outpatient headset business model. The proprietary IT platform will manage all aspects of a new virtual health center related to treatment for mental health. As the development of the new generations of our devices and the outpatient headset are developed, the digital platform will eventually manage and triangulate the relationship between the medical professional, the patient, and the manufacturer. The digital platform will handle logistics, data collection and user experience data for clinical evaluation. Additionally, there will be an app that the patients will install on their phones that will communicate with the outpatient headset. The app will upload user information that is HIPAA compliant to the IT management platform. Modules will be designed and implemented in the platform to collect biometric data. The biometric data will be utilized to evaluate patient response. A symptom exam for additional clinical validation will also be offered in the app. All data and user information will be stored in a secure, HIPAA compliant cloud computing center and access to the information will be



managed through a secure and compliant dashboard management system. The medical professional will have access to all data to monitor outpatient experience, client response and general health and wellness information.

We will leverage our IT investment to create a lead management system for mental health physicians connecting prospective patients with providers. The medical professional will be able to engage in a telehealth virtual appointment with prospective patients to complete an evaluation and assess whether the patient is a candidate for the outpatient headset program. After the professional approves the device for the patient, we will automatically prepare shipment of the device directly to the outpatient consumer from the manufacturer. We will have an internal department to monitor shipment, and to answer questions through a help desk on how to set up and use the device. The medical professional can be reimbursed for the virtual appointment via the outpatient's insurance for telehealth care which is becoming part of the new normal in the post-pandemic, digital-health world.

Additional design and implementation of modules related to social media marketing, bio-metric data collection and user experience will eventually complete the design of the IT management platform.

### *Manufacturing*

In December 2021, we entered into a quality assurance agreement with Apical Instruments, an FDA-registered manufacturer, to ensure quality assurance of our products. We currently have enough design and manufacturing support to meet all projected company design and sales goals. Our regulatory team works closely with the Apical quality team to ensure all current compliance and testing standards are adhered to. All distribution channels will rely on a collaboration between the Apical and Nexalin teams.

### *Intellectual Property*

Our commercial success depends in part on our ability to: obtain and maintain proprietary or intellectual property protection for our products, our core technologies and other know-how; operate without infringing on the proprietary rights of others; and prevent others from infringing on our proprietary or intellectual property rights. Our policy is to seek to protect our proprietary and intellectual property position by, among other methods, filing United States and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on the skills, knowledge, and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors. To help protect our proprietary know-how that is not patentable, we rely on trade secret protection and confidentiality agreements to protect our interests. As part of our hiring practices and as described in our Code of Ethics which is binding on all employees, our employees, consultants, and advisors are prohibited from disclosing confidential information and are required to assign to us the ideas, developments, discoveries and inventions important to our business.

We file patent applications directed to our key products to establish intellectual property positions. These patent applications are intended to protect these products as well as their uses in the treatment of diseases. We are the owner and inventor of two existing patent and five pending patents related to the electro-stimulation techniques related to our products and services. Our current patents cover a therapeutic electro-stimulation apparatus (the medical device) and the software used to create and administer the stimulation to the patient. We expect to file additional provisional and non-provisional patent applications and copyright protection pertaining to future Generation technology, proprietary software, and trademarks. The patent claims associated with the non-provisional patent applications will be defined and prepared in the filings. The intention is to build an intellectual property portfolio asset. Future research and development projects related to advancements in neurostimulation and neuromodulation technology will be identified and investigated for future patent filings.

Our trademark portfolio currently consists of registered trademark rights for the mark, NEXALIN TECHNOLOGY, in the United States. In connection with the ongoing development and advancement of our products and services in the United States and various international jurisdictions, we routinely seek to create protection for our marks and enhance their value by pursuing trademarks and service marks where available and when appropriate. In addition to patents and trademark protection, we rely upon unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, by using confidentiality agreements with our commercial partners, collaborators, employees and consultants, and invention assignment agreements with our employees. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

### *Competition*

We plan to be the leader in brain-based health. We compete with traditional pharmaceutical therapies. All of these have side effects, such as drug dependency as well as adverse health risks.

We also compete with several neurostimulators at the high and low end of the market as well as implanted devices. All have either a high-risk profile or uncomfortable side effects with moderate efficacy. Our products were designed as a cost-effective option to all current reimbursed treatments available to the patient.

We believe that existing neurostimulation products are either high risk, high cost and difficult to administer. In addition, they are invasive, frequently requiring surgery and multiple visits to a physician. Since many of the conditions requiring ongoing treatments, the difficulty and cost of administering them make them of limited utility for broad application.

### *Corporate Information; Recent Initial Public Offering; Employees*

We were originally formed as a Nevada corporation on October 19, 2010 as Nexalin Technology, Inc. On December 1, 2021, we completed the corporate reorganization described under the sub-section titled "Corporate Reorganization," pursuant to which Nexalin Nevada merged with and into a newly incorporated Delaware company of the same name, Nexalin and, as a result, Nexalin succeeded Nexalin Nevada and our existing shareholders exchanged each of their shares in Nexalin Nevada for one twentieth (1/20<sup>th</sup>) of a common share of the newly formed Delaware corporation. Nexalin had nominal assets and liabilities and did not conduct any operations prior to the reorganization other than its incorporation.

We completed the closing of our initial public offering on September 16, 2022. The initial public offering consisted of 2,315,000 units consisting of 2,315,000 shares of its Common Stock and 2,315,000 accompanying warrants to purchase up to 2,315,000 shares of common stock. Each share of common stock was sold together with one warrant, each to purchase one share of common stock with an exercise price of \$4.15 per share at a combined offering price of \$4.15, for gross proceeds of \$9,607,250, before deducting underwriting discounts and offering expenses. In addition, Nexalin granted the underwriters a 45-day option to purchase up to an additional 347,250 shares of common stock and/or warrants to purchase up to 347,250 shares of common stock to cover over-allotments at the initial public offering price, less the underwriting discount. The underwriters exercised their option to purchase 347,250 warrants for net proceeds of \$3,473.

A registration statement on Form S-1 (File No. 333-261989) was filed with the Securities and Exchange Commission ("SEC"), which became effective on September 15, 2022. A final

prospectus relating to the offering was filed with the SEC and is available on the SEC's website at <http://www.sec.gov>.

Our shares and warrants began trading on the Nasdaq Capital Market tier of the Nasdaq Stock Market ("Nasdaq") on September 16, 2022, under the symbols "NXL" and "NXLIW", respectively.

#### *Properties*

Our principal executive offices are located at 1776 Yorktown, Suite 550, Houston, Texas 77056. Our phone number is (832) 260-0222. Our website address is [www.nexalin.com](http://www.nexalin.com). We do not incorporate the information on or accessible through our website into this Report on Form 10-K. We have included our website address in this Annual Report on Form 10-K solely as an inactive textual reference.

#### *Human Capital Resources*

We currently have 6 full time employees and approximately 7 consultants at different times working on various projects. These consultants, and our legal and financial advisors assist us in various areas related to regulatory, engineering, research and development, sales and marketing, legal, financial and other miscellaneous tasks necessary to run our business on day-to-day basis and to facilitate the development of new products.

None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good. We have historically utilized contractors to perform many of our services. Through this process, we believe that we have attracted highly qualified professionals.

#### *Compensation and Benefits*

We believe that our future success largely depends upon our continued ability to attract and retain highly skilled employees. Medical device companies both large and small compete for a limited number of qualified applicants to fill specialized positions. To attract qualified applicants as we attempt to scale our business, we will need to offer a total rewards package consisting of base salary and cash target bonus, a comprehensive benefit package and equity compensation to select employees. Bonus opportunity and equity compensation is expected to increase as a percentage of total compensation based on level of responsibility, and actual bonus pay-out would be based on performance.

#### *Health, Wellness and Safety*

We believe that the safety and health of our employees and their families is essential to our business. Our culture is driven by a desire to do what is right, and we strive to support the well-being of our employees. We prioritize the safety and well-being of our employees even after they have faced both mental and physical challenges related to the COVID-19 pandemic.

#### *Implications of Being an Emerging Growth Company and a Smaller Reporting Company*

We qualify as an "emerging growth company," as defined in the Jumpstart Our Business Start-ups Act of 2012, as amended, or the JOBS Act. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from some of the reporting requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to present only two years of audited financial statements and only two years of related management's discussion and analysis of financial condition and results of operations disclosures;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act;
- not being required to comply with any requirements that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may take advantage of these exemptions until the last day of our fiscal year following the fifth anniversary of the completion of our IPO which was completed on September 16, 2022. However, if any of the following events occur prior to the end of such five-year period, (i) our annual gross revenue exceeds \$1.07 billion, (ii) we issue more than \$1.0 billion of non-convertible debt in any three-year period or (iii) we become a "large accelerated filer," (as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), we will cease to be an emerging growth company prior to the end of such five-year period. We will be deemed to be a "large accelerated filer" at such time that we (a) have an aggregate worldwide market value of common equity securities held by non-affiliates of \$700 million or more as of the last business day of our most recently completed second fiscal quarter, (b) have been required to file annual and quarterly reports under the Exchange Act, for a period of at least twelve months and (c) have filed at least one annual report pursuant to the Exchange Act. Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. We have elected to take advantage of this extended transition period.

We are also a "smaller reporting company" as defined in the Exchange Act. We may take advantage of certain of the scaled disclosures available to smaller reporting companies until the fiscal year following the determination that our voting and non-voting common stock held by non-affiliates is more than \$250 million measured on the last business day of our second fiscal quarter, or our annual revenues are less than \$100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than \$700 million measured on the last business day of our second fiscal quarter.

## **ITEM 1A RISK FACTORS**

*Investing in our common stock and warrants to acquire common stock is speculative and involves a high degree of risk including the risk of a loss of your entire investment. Before you invest in our common stock or warrants, you should carefully consider the following risk factors. These risk factors contain, in addition to historical information,*

forward looking statements that involve risks and uncertainties. Our actual results could differ significantly from the results discussed in the forward-looking statements. The occurrence of any of the adverse developments described in the following risk factors and in the documents incorporated herein by reference could materially and adversely harm our business, financial condition, results of operations or prospects. In such event, the value of our common stock could decline, and you could lose all or a substantial portion of the money that you pay for our common stock which may include the exercise price of any warrants. In addition, the risks and uncertainties discussed below are not the only ones we face. Our business, financial condition, results of operations or prospects could also be harmed by risks and uncertainties not currently known to us or that we currently do not believe are material, and these risks and uncertainties could result in a complete loss of your investment. A summary of our risk factors is as follows:

#### *Risks Related to Our Financial Position and Capital Needs*

**We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.**

We are a Delaware corporation with a limited operating history. We have funded our operations to date primarily with proceeds from private investors and the sale of our stock, including the proceeds from our initial public offering completed in September 2022. We have had only limited sales of our products and services to date. For the year ended December 31, 2022, we incurred a comprehensive loss in the amount of \$1,661,503. Our accumulated deficit at December 31, 2022 was \$72,389,340.

We have devoted a substantial portion of our financial resources and efforts to research and development, including preclinical studies and clinical trials. We are still in the early stages of development of our products.

We expect to continue to incur significant expenses and operating losses over the next several years. Our net losses may fluctuate substantially from quarter to quarter and year to year. We anticipate that our expenses will increase significantly as we:

- continue our ongoing and planned preclinical and clinical development of our existing and next Generation devices;
- initiate preclinical studies and clinical trials for any additional products that we may pursue in the future;
- seek to discover and develop additional treatment indications;
- seek regulatory approvals for any products that successfully complete clinical trials;
- ultimately establish sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize any product for which we may obtain regulatory approval and intend to commercialize on our own;
- maintain, expand and protect our intellectual property portfolio;
- engage additional clinical, scientific, manufacturing and controls personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- incur additional legal, accounting and other expenses associated with operating as a public company.

To become and remain profitable, we and our collaborators must succeed in developing and eventually commercializing future and existing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our products and preclinical program, obtaining regulatory approval, manufacturing, marketing and selling any products for which we may obtain regulatory approval, as well as discovering and developing additional products. Again, we are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with product development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. If we are required by regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our products, our expenses could increase.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our common stock and could impair our ability to raise capital, expand our business, maintain our research and development efforts or continue our operations. A decline in the value of our common stock could also cause you to lose all or part of your investment.

**Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.**

We commenced active operations in 2010, and our operations to date have been largely focused on raising capital, identifying and developing our products and preclinical program, broadening our expertise in the development of our products and undertaking preclinical studies and conducting early-stage clinical trials. As a result of the FDA reclassification ruling in December 2019, we had to suspend marketing of our Gen-1 medical device for the treatment of anxiety and insomnia. We are presently evaluating whether to proceed with amending our prior application with the FDA for the treatment of insomnia and anxiety or filing new applications 510(k) for our next Generation devices.

Although we have developed a second-Generation medical device, it has not completed regulatory filings with the FDA for marketing or sales in the United States. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

**We may require substantial additional funding to meet our financial needs and to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to delay, reduce or altogether cease our product development programs or commercialization efforts.**

We are currently not cash flow positive and are not certain when and if we will be cash flow positive. We incurred a comprehensive loss in the amount of \$1,661,503 for the year ended December 31, 2022. While we believe that the net proceeds from our recently completed initial public offering will enable us to fund our operating expenses and capital expenditure requirements for the next 12 months, we may still need to obtain substantial additional funding in connection with our continuing operations and planned activities.

Our future capital requirements will depend on many factors, including:

- the timing, progress and results of our ongoing clinical trials of our products;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials of other products that we may pursue;

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- the number and development requirements of other products that we may pursue;
- our ability to establish collaborations on favorable terms, if at all;
- the costs, timing and outcome of regulatory review of our products;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our products for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our products for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- the costs of operating as a public company.

Identifying potential products and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to continue our regulatory approvals and achieve product sales. In addition, our products, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that are cleared under FDA review. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether cease our research and development programs or future commercialization efforts.

**Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or products.**

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through equity offerings. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or products or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to a third party to develop and market products that we would otherwise prefer to develop and market ourselves.

*Risks Related to the Development of Our Products and Preclinical Program*

**We depend on the success of our future products, some of which are in clinical development but have not completed advanced clinical trials. If we lose our existing or cannot obtain future regulatory approval for and successfully commercialize one or more of our products or if we experience significant delays in doing so, we may never become profitable.**

The success of our products and preclinical program will depend on several additional factors, including:

- successful completion of preclinical studies and requisite clinical trials;
- performing preclinical studies and clinical trials in compliance with the FDA or any comparable regulatory authority requirements;

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- receipt of marketing approvals from applicable regulatory authorities;
- the ability of collaborators to manufacture sufficient quantity of product for development, clinical trials or potential commercialization;
- obtaining and maintaining patent, trademark and trade secret protection, and regulatory exclusivity for our products and preclinical program;
- making arrangements with third parties for manufacturing capabilities;
- launching commercial sales of products, if and when approved, whether alone or in collaboration with others;
- acceptance of the therapies, if and when approved, by healthcare providers, physicians, clinicians, patients and third-party payors;
- competing effectively with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement; and
- protecting our rights in our intellectual property portfolio.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our products, which would harm our business.

**Our products and product candidates may be subject to reclassification by the FDA, and a change in the classification may have an adverse impact on our revenues or our abilities to obtain necessary regulatory approvals.**

Originally, our technology was cleared for the treatment of anxiety, depression and insomnia. Each treatment indication with this technology was classified as class III from a risk tolerance standpoint at the FDA. In December of 2019, the FDA passed a new ruling that separated anxiety and insomnia from the treatment of depression. CES devices that treat anxiety and insomnia were reclassified as class II medical devices and require special control trials to be initiated, as well as the filing of a new 510(k) application for previously approved devices. The FDA continued to classify the treatment of depression for cranial stimulation as a class III high risk device. In order to receive approval for treatment for depression, our devices will require a new pre-market application for this indication. We have decided not to pursue a depression indication for our Gen-1 device at such time.

Any further such reclassification by the FDA of an indication from a certain class of device to another during our development or post-commercialization for that indication could have a significant adverse impact due to the more rigorous and lengthy approval process required for a higher risk class medical device. Such a change in classification can significantly increase development costs and prolong the time for development and approval, thus delaying revenues. A reclassification of an indication after approval from a certain class of device to another could result in a change in classification for reimbursement, and there could be a significant negative impact on our revenues relatedly.

**Success in preclinical studies or clinical trials may not be indicative of results in future clinical trials.**

Success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Our products may fail to show the desired safety and efficacy in all clinical trials.

**If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.**

We may not be able to initiate, continue or complete clinical trials of any product candidate that we develop if we and our collaborators are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or other comparable regulatory authority. We have limited experience enrolling patients in our clinical trials and cannot predict how successful we will be in enrolling patients in future clinical trials.

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**Public health threats, including those related to the novel strain of coronavirus, SARS-CoV-2 (which causes the disease now called COVID-19), have had, and could continue to have an adverse effect on our operations.**

Public health threats have, and could continue to, adversely affect our ongoing or planned research and development activities. In particular, SARS-CoV-2, which causes the disease now called COVID-19, was first reported to have surfaced in Wuhan, China in December 2019, and has since spread globally, including to every state in the United States. The outbreak of COVID-19 has severely impacted global economic activity (including adversely affecting the global supply chain) and caused significant volatility and negative pressure in financial markets. The global impact of the outbreak has been rapidly evolving and many countries, including the United States and China, have reacted over time by instituting quarantines, mandating business and school closures and restricting travel. As a result, the COVID-19 pandemic has negatively impacted almost every industry directly or indirectly.

The COVID-19 pandemic has delayed our clinical trials and our receipt of marketing approvals from the FDA and also negatively impacted our ability to complete our proposed joint venture in China and Asia and the ability of our distributor and proposed joint venture partner, Wider to operate in China. Such pandemic also has reduced, and continues to reduce, participation in our clinical trials, due to both travel restrictions and a general unwillingness of subjects to travel. The COVID-19 pandemic had severe adverse effects on the economy in China in 2021 and 2022 and continues to negatively impact the China economy. We cannot presently predict the scope and severity of any other potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage, including our proposed joint venture partner, the suppliers, clinical trial sites, regulators and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted.

Relatedly, the spread of an infectious disease, including COVID-19, may also result in the inability of our suppliers to deliver components or raw materials on a timely basis. Such events may result in a period of business and manufacturing disruption, and in reduced operations, any of which could materially affect our business, financial condition and results of operations. The extent to which the coronavirus impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain the coronavirus or treat its impact, among others.

#### *Risks Related to Our Dependence on Third Parties*

**We rely on third parties to conduct the clinical trials for our products, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials or failing to comply with applicable regulatory requirements.**

We rely on third parties, such as research institutions and Wider, which is based in China, to conduct some of our clinical trials. Our reliance upon research institutions, including hospitals, clinics and academics, provides us with less control over the timing and cost of clinical trials and the ability to recruit subjects. If we are unable to reach agreement with suitable research institutions on acceptable terms, or if any resulting agreement is terminated, we may be unable to quickly replace the research institution with another qualified institution on acceptable terms. Even if we do replace the institution, we may incur additional costs to conduct the trial at the new institution. We may not be able to secure and maintain suitable research institutions to conduct our clinical trials.

**We rely on a collaboration with a third party for the quality assurance of our products, and we may seek additional collaborations in the future. If those collaborations are not successful, we may not be able to capitalize on the market potential of these products.**

We are a party to a quality assurance agreement with a third party for the quality assurance of our products and may enter into additional collaborations in the future. We are dependent upon the success of our current and any future collaborators in performing their responsibilities in connection with the relevant collaboration. If we fail to maintain these collaborative relationships for any reason, we would need to perform the activities that we currently anticipate would be performed by our collaborators on our own at our sole expense. This could substantially increase our capital needs, and we may not have the capability or financial capacity to undertake these activities on our own, or we may not be able to find other collaborators on acceptable terms, or at all. This may limit the programs we are able to pursue and result in significant delays in the development, sale and manufacture of our product candidates and products, and may have a material adverse effect on our business, financial condition and results of operations.

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Our dependence upon our current and potential future collaborations exposes us to a number of risks, including that our collaborators (i) may fail to cooperate or perform their contractual obligations, including financial obligations, (ii) may choose to undertake differing business strategies or pursue alternative technologies or (iii) may take an opposing

view regarding ownership of clinical trial results or intellectual property.

Due to these factors and other possible events, we could suffer delays in the research, development or commercialization of our product candidates and future products or we may become involved in litigation or arbitration, which could be time consuming and expensive. We additionally may be compelled to split revenue with our collaborators, which could have a material adverse effect on our business, financial condition, and results of operations.

#### *Risks Related to the Commercialization of Our Products*

**Even if any of our products receives marketing approval, it may fail to achieve the degree of market acceptance by healthcare providers, physicians, clinicians, patients, third-party payors and others in the medical community necessary for commercial success.**

The degree of market acceptance of our products, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments;
- the potential and perceived advantages and disadvantages of the products, including cost and clinical benefit relative to alternative treatments;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of healthcare providers, physicians, and clinicians to prescribe these therapies;
- acceptance by healthcare providers, physicians, clinicians, patients, operators of hospitals, including in-hospital formularies, and treatment facilities and parties responsible for coverage and reimbursement of the product;
- the availability of coverage and adequate reimbursement by third-party payors and government authorities;
- the ability to manufacture our product in sufficient quantities and yields;
- the strength and effectiveness of marketing and distribution support;
- the prevalence and severity of any side effects;
- limitations or warnings, including distribution or use restrictions, contained in the product's approved labelling;
- the approval of other new products for the same indications; and
- the timing of market introduction of the approved product as well as competitive products.

Any failure by any of our existing or future products that obtain regulatory approval to achieve market acceptance or commercial success would have a material adverse effect on our business prospects.

**We may eventually compete for product sales with other companies, many of which will have greater resources or capabilities than we have, or may succeed in developing better products or in developing products more quickly than we do, and we may not compete successfully with them.**

Our industry is competitive and has been evolving rapidly with not only existing treatment options, but also the introduction of new technologies and products as well as the market activities of industry participants. We compete or may eventually compete with other companies and organizations that are marketing or developing therapies for our targeted disease indications, based on traditional pharmaceutical, medical device, or other neurostimulation therapy and technologies.

We also face competition in the neurostimulation field from academic institutions and governmental agencies. Many of our current and potential competitors have greater financial and human resources than we have, including more experience in research and development and more established sales, marketing and distribution capabilities.

We anticipate that competition in our industry will increase. In addition, the health care industry is characterized by rapid technological change, resulting in new product introductions and other technological advancements. Our competitors may develop and market products that render product candidates now or under development by us in the future, or any products manufactured or marketed by us, non-competitive or otherwise obsolete.

**Coverage and adequate reimbursement may not be available for our current or any future products, which could make it difficult for us to sell profitably, if approved.**

Market acceptance and sales of any products that we commercialize, if approved, will depend in part on the extent to which reimbursement for these products and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations and other private health insurers. Third-party payors decide which therapies they will pay for and establish reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any products that we develop will be made on a payor-by-payor basis. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and adequate reimbursement for the product. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Each payor determines whether it will provide coverage for a therapy, what amount it will pay for the therapy and on what tier of its list of covered products, or formulary, it will be placed. The position on a payor's formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products, and providers are unlikely to prescribe our products, unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of our products and their administration.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Third-party payors have attempted to control costs by limiting coverage and limited reimbursement for medications and certain treatments utilizing digital technologies. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our current and any future products that we develop.

**Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.**

We face an inherent risk of product liability exposure related to the testing of our products in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our products or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- reduced resources of our management to pursue our business strategy;

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- decreased demand for any products or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- product recalls, withdrawals or labelling, marketing or promotional restrictions;
- significant costs to defend the resulting litigation;
- substantial monetary awards paid to clinical trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We currently hold \$1 million in product liability insurance coverage in the aggregate, with a per incident limit of \$1 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our products. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

#### *Risks Related to Our Business and Managing Our Growth*

##### **Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.**

Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of any of our products, commercialization, manufacturing and sales and marketing personnel, will be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize our products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue our growth strategy will be limited.

##### **We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.**

As of December 31, 2022, we had 6 full-time employees and 7 consultants. As the clinical development of our products progresses, we also expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of research, product development and regulatory affairs, including a sales and marketing team for our existing products. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

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##### **Significant disruptions of our information technology systems or data security incidents could result in significant financial, legal, regulatory, business and reputational harm to us.**

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store, process and transmit large amounts of sensitive information, including intellectual property, proprietary business information, personal information and other confidential information. It is critical that we do so in a secure manner to maintain the confidentiality, integrity and availability of such sensitive information. We have also outsourced elements of our operations, including elements of our information technology infrastructure, to third parties and, as a result, we manage a number of third-party vendors who may or could have access to our computer networks or our confidential information. In addition, many of those third parties in turn subcontract or outsource some of their responsibilities to other third parties. While all information technology operations are inherently vulnerable to inadvertent or intentional security breaches, incidents, attacks and exposures, the accessibility and distributed nature of our information technology systems, and the sensitive information stored on those systems, make such systems potentially vulnerable to unintentional or malicious, internal and external attacks on our technology environment. Potential vulnerabilities can be exploited from inadvertent or intentional actions of our employees, third-party vendors, or business partners or by malicious third parties. Attacks of this nature are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives (including industrial espionage) and expertise, including organized criminal groups, "hacktivists," nation states and others. In addition to the extraction of sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. In addition, the prevalent use of mobile devices increases the risk of data security incidents.

Significant disruptions of our third-party vendors' information technology systems or other similar data security incidents could adversely affect our business operations and result in the loss, misappropriation and unauthorized access, use or disclosure of, or the prevention of access to, sensitive information, which could result in financial, legal,

regulatory, business and reputational harm to us. In addition, information technology system disruptions, whether from attacks on our technology environment or from computer viruses, natural disasters, terrorism, war or telecommunication and electrical failures, could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

There is no way of knowing with certainty whether we have experienced any data security incidents that have not been discovered. While we have no reason to believe this to be the case, attackers have become very sophisticated in the way they conceal access to systems, and many companies that have been attacked are not aware that they have been attacked. Any event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our patients or employees, could disrupt our business, harm our reputation, compel us to comply with applicable federal and state breach notification laws and foreign law equivalents, subject us to time-consuming, distracting and expensive litigation, regulatory investigation and oversight or mandatory corrective action, require us to verify the correctness of database contents or otherwise subject us to liability under laws, regulations and contractual obligations, including those that protect the privacy and security of personal information. This could result in increased costs to us, and result in significant legal and financial exposure and reputational harm. In addition, any failure or perceived failure by us or our vendors or business partners to comply with our privacy, confidentiality or data security-related legal or other obligations to third parties, or any further security incidents or other inappropriate access events that result in the unauthorized access, release or transfer of sensitive information, which could include personally identifiable information, may result in governmental investigations, enforcement actions, regulatory fines, litigation or public statements against us by advocacy groups or others, and could cause third parties, including clinical sites, regulators or current and potential partners, to lose trust in us, or we could be subject to claims by third parties that we have breached our privacy- or confidentiality-related obligations. Moreover, data security incidents and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. While we have implemented security measures intended to protect our information technology systems and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or security incidents.

**If we engage in future acquisitions or strategic collaborations, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.**

From time to time, we may evaluate various acquisitions and strategic collaborations, including licensing or acquiring intellectual property rights, technologies or businesses, as deemed appropriate to carry out our business plan. Any potential acquisition or strategic collaboration may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic partnership, merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or products and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

**We are subject to the risks of conducting business internationally.**

On February 24, 2022, Russia launched an invasion in Ukraine which has increased supply interruptions throughout the world and in the United States and may hinder our ability to find the materials we need to make our products. Although, to date, there has been minimal effect upon our business, supply disruptions could make it harder for us to find favorable pricing and reliable sources for the materials we need, putting upward pressure on our costs and increasing the risk that we may be unable to acquire the materials and services we need to continue to make certain products.

*Risks Related to Doing Business in China*

**The medical industry in China is highly regulated and such regulations are subject to change which may affect approval and commercialization of our products.**

A material portion of our research is expected to be conducted in China through the potential Joint Venture, which we believe confers clinical, commercial and regulatory advantages, but may subject the potential Joint Venture (and also potentially us) to significant regulatory, liquidity, and enforcement risks. The medical industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. In recent years, the regulatory framework in China regarding the medical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. Any such changes or amendments may result in increased compliance costs on our business or cause delays in or prevent the successful development or commercialization of our products in China and reduce the current benefits we believe are available to us from researching our products in China. The People's Republic of China, or PRC, authorities have become increasingly vigilant in enforcing laws in the medical industry and any failure by us or our partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our business activities in China. We believe our strategy and approach are aligned with the PRC government's regulatory policies, but we cannot ensure that our strategy and approach will continue to be aligned. In the event that there are changes, we and the potential Joint Venture will take any and all actions to remain in compliance with any such laws or regulations or detailed implementations and interpretations thereof.

**There may be difficulties in effecting service of legal process, enforcing foreign judgments or bringing actions in China against us based on foreign laws.**

We expect to conduct a material portion of our research in China through the potential Joint Venture. Also, the potential Joint Venture is expected to be formed under the laws of Hong Kong and is expected to be physically located in Hong Kong. Our potential joint venture partner, Wider, is located in China. As a result, it may be difficult to effect service of process upon the potential Joint Venture inside China. It may also be difficult to enforce in U.S. courts judgments obtained in U.S. courts based on the civil liability provisions of the U.S. federal securities laws against the potential Joint Venture. In addition, there is uncertainty as to whether the courts of the PRC would recognize or enforce judgments of U.S. courts against the potential Joint Venture predicated upon the civil liability provisions of the securities laws of the United States or any state.

It may be difficult for us to enforce our rights with respect to the potential Joint Venture. The recognition and enforcement of foreign judgments are provided for under the PRC



Civil Procedures Law. PRC courts may recognize and enforce foreign judgments in accordance with the requirements of the PRC Civil Procedures Law based either on treaties between China and the country where the judgment is made or on principles of reciprocity between jurisdictions. China does not have any treaties or other forms of written arrangement with the United States that provide for the reciprocal recognition and enforcement of foreign judgments. In addition, according to the PRC Civil Procedures Law, the PRC courts will not enforce a foreign judgment by us against Wider or the potential Joint Venture if they decide that the judgment violates the basic principles of PRC laws or national sovereignty, security, or the public interest. As a result, it is uncertain whether and on what basis a PRC court would enforce a judgment rendered by a court in the United States.

**It may be difficult for overseas regulators to conduct investigations or collect evidence within China.**

It may be difficult for you or overseas regulators, such as the Securities and Exchange Commission (SEC), the Department of Justice (DOJ) and other authorities of the United States, to conduct investigations or collect evidence within China. For example, in China, there are significant legal and other obstacles to obtaining information, documents and materials needed for regulatory investigations or litigation outside China or otherwise with respect to foreign entities. Although the authorities in China may establish a regulatory cooperation mechanism with the securities regulatory authorities of another country or region to implement cross-border supervision and administration, such regulatory cooperation with the securities regulatory authorities in the United States may not be efficient in the absence of mutual and practical cooperation mechanism. Furthermore, according to Article 177 of the PRC Securities Law, which became effective in March 2020, no overseas securities regulator is allowed to directly conduct investigation or evidence collection activities within the territory of the PRC. Accordingly, without the consent of the competent PRC securities regulators and relevant authorities, no entity or individual may provide the documents and materials relating to securities business activities to overseas parties. While detailed interpretation of or implementing rules under Article 177 have yet to be promulgated, the inability for an overseas securities regulator to directly conduct investigation or evidence collection activities within China may further increase difficulties faced by you in protecting your interests.

**The PRC's economic, political and social conditions, as well as governmental policies, could affect the business environment and financial markets in China, and our ability to operate our business, maintain our liquidity and keep our access to capital.**

We expect that a portion of our operations will be conducted in China through the potential Joint Venture. Accordingly, our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in China. China's economy differs from the economies of developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources. While the PRC economy has experienced significant growth over the past thirty years, growth has been uneven across different regions and among various economic sectors of China. The PRC government has implemented various measures to encourage economic development and guide the allocation of resources. Some of these measures may benefit the overall PRC economy but may have a negative effect on us. For example, our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations that are currently applicable to us. In addition, in the past the PRC government implemented certain measures, including interest rate increases, to control the pace of economic growth. These measures may cause decreased economic activity in China, which may adversely affect our business and results of operation. More generally, if the business environment in China deteriorates from the perspective of domestic or international investment, our business in China may also be adversely affected.

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**Uncertainties with respect to the PRC legal system could adversely affect us.**

The PRC legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions under the civil law system may be cited for reference but have limited precedential value.

In 1979, the PRC government began to promulgate a comprehensive system of laws and regulations governing economic matters in general. The overall effect of legislation over the past four decades has significantly enhanced the protection afforded to various forms of foreign investments in China. However, China has not developed a fully integrated legal system, and recently enacted laws and regulations may not sufficiently cover all aspects of economic activities in China. In particular, the interpretation and enforcement of these laws and regulations involve uncertainties. Since PRC administrative and court authorities have significant discretion in interpreting and implementing statutory provisions and contractual terms, it may be difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy. These uncertainties may affect our judgment on the relevance of legal requirements and our ability to enforce our contractual rights or tort claims. In addition, the regulatory uncertainties may be exploited through unmerited or frivolous legal actions or threats in attempts to extract payments or benefits from us.

In addition, any administrative and court proceedings in China may be protracted, resulting in substantial costs and diversion of resources and management attention.

In May 2019, the Cyberspace Administration of China ("CAC") issued strict guidelines for the collection and use of data by operators in China. At this time, Wider does not share any data from any hospital setting or research setting with Nexalin and Nexalin does not share any data from any hospital setting or research setting with Wider. All clinical data, patient data, provider data associated with China and the U.S. do not affect the design or statistical interpretation of preclinical or clinical studies in either country.

**Uncertainties in the interpretation and enforcement of Chinese laws and regulations could limit the legal protections available to us.**

The PRC legal system is based on written statutes and prior court decisions have limited value as precedents. Since these laws and regulations are relatively new and the PRC legal system continues to rapidly evolve, the interpretations of many laws, regulations and rules are not always uniform and enforcement of these laws, regulations and rules involves uncertainties.

From time to time, we may have to resort to administrative and court proceedings to enforce our legal rights, most notably our rights with respect to the potential Joint Venture. However, since PRC administrative and court authorities have significant discretion in interpreting and implementing statutory and contractual terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy than in more developed legal systems. Furthermore, the PRC legal system is based in part on government policies and internal rules. As a result, we may not be able to keep ourselves updated with these policies and rules in time. Such uncertainties, including uncertainty over the scope and effect of our contractual, property (including intellectual property) and procedural rights, could materially and adversely affect our business and impede our ability to continue our operations.

**Restrictions on foreign currency may limit our ability to receive and use our revenue effectively.**

The PRC government imposes controls on the conversion of the Renminbi into foreign currencies and, in certain cases, the remittance of foreign currency out of China. To date, the payments we have received from Wider have been in United States dollars, although in the future, payments from Wider or from the potential Joint Venture may be in Renminbi. Under existing PRC foreign exchange regulations, payments of current account items, including profit distributions, interest payments and trade and service-related foreign exchange transactions, can be made in foreign currencies without prior approval of SAFE, by complying with certain procedural requirements. However, approval from or registration with appropriate government authorities is required where Renminbi is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of loans denominated in foreign currencies. As a result, we would need to obtain approval from SAFE to use cash generated from our operations to pay off any debt in a currency other than Renminbi owed to entities outside China, or to make other capital expenditure payments outside China in a currency other than Renminbi. The PRC government may restrict access to foreign currencies for current account transactions in the future. The foreign exchange control system could prevent us from obtaining sufficient foreign currencies to satisfy our foreign currency demands.

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**Fluctuation in exchange rates could have a negative effect on our results of operations and the value of your investment.**

The value of the Renminbi against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in political and economic conditions in China and by China's foreign exchange policies. Since June 2010, the Renminbi has fluctuated against the U.S. dollar, at times significantly and unpredictably. On November 30, 2015, the Executive Board of the International Monetary Fund, or IMF, completed the regular five-year review of the basket of currencies that make up the Special Drawing Right, or the SDR, and decided that with effect from October 1, 2016, the Renminbi is determined to be a freely usable currency and will be included in the SDR basket as a fifth currency, along with the U.S. dollar, the euro, the Japanese yen and the British pound. Since the fourth quarter of 2016, the Renminbi has depreciated significantly in the backdrop of a surging U.S. dollar and persistent capital outflows of China. With the development of the foreign exchange market and progress toward interest rate liberalization and Renminbi internationalization, the PRC government may in the future announce further changes to the exchange rate system, and we cannot assure you that the Renminbi will not appreciate or depreciate significantly in value against the U.S. dollar in the future. It is difficult to predict how market forces or PRC or U.S. government policy may impact the exchange rate between the Renminbi and the U.S. dollar in the future.

Very limited hedging options are available in China to reduce our exposure to exchange rate fluctuations. As of the date Form 10-K, we have not entered into any hedging transactions in an effort to reduce our exposure to foreign currency exchange risk. While we may decide to enter into hedging transactions in the future, the availability and effectiveness of these hedges may be limited and we may not be able to adequately hedge our exposure or at all. In addition, our currency exchange losses may be magnified by PRC exchange control regulations that restrict our ability to convert Renminbi into foreign currency or to convert foreign currency into Renminbi.

**The approval of the CSRC, and other compliance procedures may be required in connection with any offering we may make and, if required, we cannot predict whether we will be able to obtain such approval.**

We do not have any operations in China and will not have any operations other than the potential Joint Venture following its formation, of which there can be no assurance. As of the date of this Form 10-K, (i) our business operations are carried on outside of China; and (ii) we do not maintain any variable interest entity structure or operate any data center in China. We do not believe that sales of our devices to Wider to date constitute doing business in China. We may still be subject to PRC laws relating to, among others, data security and restrictions over foreign investments due to the complexity of the regulatory regime in China, and the recent statements and regulatory actions by the PRC government relating to data security may affect our business operations in China or even our ability to offer securities in the United States. Our securities are not being offered or sold directly or indirectly in China to or for the benefit of, legal or natural persons of the PRC. Therefore, we have not obtained the approval from either the China Securities Regulatory Commission (the "CSRC") or the Cyberspace Administration of China (the "CAC") for any offering we may make in the future, and we do not intend to obtain the approval from either the CSRC or the CAC in connection with any such future offering, since we do not believe that such approval is required under these circumstances. Under the PRC's current legal system, Chinese citizens have the right to purchase securities publicly issued by overseas companies through legal channels and enjoy corresponding benefits of such ownership. Ownership of such securities does not require approval from the CSRC or the CAC.

On the website of the CSRC, the CSRC provides that in accordance with current laws and regulations, domestic Chinese residents can invest in overseas securities markets through legal channels such as purchasing qualified domestic institutional investor (QDII) fund product shares and participating in Shanghai Hong Kong stock transactions.

There can be no assurance however, that regulators in China will not take a contrary view or will not subsequently require us to undergo the approval procedures and subject us to penalties for non-compliance. The approval of the CSRC or the CAC, and other compliance procedures may be required in connection with any offering we may make and, if required, we cannot predict whether we will be able to obtain such approval.

**Recent regulatory developments in China may subject the potential Joint Venture to additional regulatory review and disclosure requirement, expose the potential Joint Venture to government interference, or otherwise restrict our ability to offer securities and raise capital outside China, all of which could materially and adversely affect our business and the value of our securities.**

In light of the recent statements by the Chinese government indicating its intention to exert more oversight and control over overseas offerings of China-based companies and the proposed CAC review for certain data processing operators in China, we may adjust our business operations in the future, to comply with PRC laws regulating our industry and our business operations through the potential Joint Venture. However, such efforts may not be completed in a liability-free manner or at all. We cannot guarantee that we will not be subject to PRC regulatory inspection and/or review relating to cybersecurity, especially when there remains significant uncertainty as to the scope and manner of the regulatory enforcement. If the potential Joint Venture is subject to regulatory inspection and/or review by the CAC or other PRC authorities or are required by them to take any specific actions, it could cause suspension or termination of the future offering of our securities, disruptions to our operations, result in negative publicity regarding our company, and divert our managerial and financial resources. The potential Joint Venture may also be subject to fines or other penalties, which could materially and adversely affect our business, financial condition, and results of operations.

We may be subject to PRC laws relating to, among others, data security and restrictions over foreign investments in value-added telecommunications services and other industry sectors set out in the Special Administrative Measures (Negative List) for the Access of Foreign Investment (2020 Edition). Specifically, we may be subject to PRC laws relating to the collection, use, sharing, retention, security, and transfer of confidential and private information, such as personal information and other data. These PRC laws apply not only to third-party transactions, but also to transfers of information between us and our wholly foreign-owned enterprises in China, and other parties with which we have commercial relations. These PRC laws and their interpretations and enforcement continue to develop and are subject to change, and the PRC government may adopt other rules and restrictions in the future. The recent regulatory developments in China, in particular with respect to restrictions on China-based companies raising capital offshore, and the government-led cybersecurity reviews of certain companies with VIE structure, may lead to additional regulatory review in China over our financing and capital raising activities in the United States. Pursuant to the PRC Cybersecurity Law, which was promulgated by the Standing Committee of the National People's Congress on November 7, 2016 and took effect on June 1, 2017, personal information and important data collected and generated by a critical information infrastructure operator in the course of its operations in China must be stored in China, and if a critical information infrastructure operator purchases internet products and services that affect or may affect national security, it should be subject to cybersecurity review by the CAC.

The PRC Cybersecurity Law also establishes more stringent requirements applicable to operators of computer networks, especially to operators of networks which involve critical information infrastructure. The PRC Cybersecurity Law contains an overarching framework for regulating Internet security, protection of private and sensitive information, and safeguards for national cyberspace security and provisions for the continued government regulation of the Internet and content available in China. The PRC Cybersecurity Law emphasizes requirements for network products, services, operations and information security, as well as monitoring, early detection, emergency response and reporting. Due to the lack of further interpretations, the exact scope of "critical information infrastructure operator" remains unclear.

On July 10, 2021, the CAC publicly issued the Cybersecurity Review Measures (the "Draft Measures") for public comments until July 25, 2021. According to the Draft Measures, the scope of cybersecurity reviews is extended to data processing operators engaging in data processing activities that affect or may affect national security. The Draft Measures further requires that any operator applying for listing on a foreign exchange must go through cybersecurity review if it possesses personal information of more than one million users. According to the Draft Measures, a cybersecurity review assesses potential national security risk that may be brought about by any procurement, data processing, or overseas listing. The review focuses on several factors, including, among others, (1) the risk of theft, leakage, corruption, illegal use or export of any core or important data, or a large amount of personal information, and (2) the risk of any critical information infrastructure, core or important data, or a large amount of personal information being affected, controlled or maliciously exploited by a foreign government after a company is listed overseas. While the Draft Measures have been released for consultation purposes, there is still uncertainty regarding the final content of the Draft Measures, its adoption timeline or effective date, its final interpretation and implementation, and other aspects. Furthermore,

the Standing Committee of the National People's Congress passed the Personal Information Protection Law of the PRC ("PIPL"), which became effective November 1, 2021, and requires general network operators to obtain a personal information protection certification issued by recognized institutions in accordance with the CAC regulation before such information can be transferred out of China.

Additionally, the Company does not currently believe any of the Company's scientific data resulting from activities in China to be conducted by the potential Joint Venture would fall within the Measures for the Management of Scientific Data promulgated by the General Office of the PRC State Council. Therefore, we do not believe the PRC would prevent us from seeking foreign approval and commercialization of our product candidates. In the event the potential Joint Venture becomes subject to cybersecurity inspection and/or review by the CAC or other PRC authorities or are required by them to take any specific actions, we and the potential Joint Venture will take any and all actions to remain in compliance with any such laws or regulations or detailed implementations and interpretations thereof.

On July 30, 2021, in response to the recent regulatory developments in China and actions adopted by the PRC government, the Chairman of the SEC issued a statement requesting additional disclosures from offshore issuers with China-based operating companies before their registration statements will be declared effective, including detailed disclosure related to VIE structures and whether the VIE and the issuer, when applicable, received or were denied permission from the PRC authorities to list on U.S. exchanges and the risks that such approval could be denied or rescinded.

On August 1, 2021, the CSRC stated that it had taken note of the new disclosure requirements announced by the SEC regarding the listings of Chinese companies and the recent regulatory development in China, and that the securities regulators in both countries should strengthen communications on regulating China-related issuers. In light of our business operations, we should not be required to undergo the CAC review for any offering that we may make. However, if the enacted version of the Draft Measures mandates clearance of cybersecurity review and other specific actions to be completed by companies aiming to offer securities outside China, we cannot assure you that the PRC regulatory authorities will not take a contrary view or will not subsequently require us to undergo the approval procedures and subject us to penalties for non-compliance, or that if we are required to obtain such clearance, such clearance can be timely obtained, or at all. If the potential Joint Venture becomes subject to cybersecurity inspection and/or review by the CAC or other PRC authorities or are required by them to take any specific actions, it could cause suspension or termination of the future offering of our securities, disruptions to our operations, result in negative publicity regarding our company, and divert our managerial and financial resources. We may also be subject to significant fines or other penalties, which could materially and adversely affect our business, financial condition and results of operations. In the event the potential Joint Venture becomes subject to cybersecurity inspection and/or review by the CAC or other PRC authorities or are required by them to take any specific actions, we and the potential Joint Venture will take any and all actions to remain in compliance with any such laws or regulations or detailed implementations and interpretations thereof.

**The PRC government has significant influence by enforcing existing rules and regulation, adopting new ones, or changing relevant industrial policies in a manner that may materially increase our compliance cost, change relevant industry landscape or otherwise cause significant changes to our business operations in China, which could result in material and adverse changes in our operations and cause the value of our securities to significantly decline or be worthless.**

The PRC government has significant influence by allocating resources, providing preferential treatment to particular industries or companies, or imposing industry-wide policies on certain industries. The PRC government may also amend or enforce existing rules and regulation, or adopt ones, which could materially increase our compliance costs of the potential Joint Venture, change the relevant industry landscape, or cause significant changes to the potential Joint Venture business operations in China. In addition, the PRC regulatory system is based in part on government policies and internal guidance, some of which are not published on a timely basis, or at all, and some of which may even have a retroactive effect. We may not be aware of all non-compliance incidents at all times, and we may face regulatory investigation, fines and other penalties as a consequence. As a result of the changes in the industrial policies of the PRC government, including the amendment to and/or enforcement of the related laws and regulations, companies with China-based operations, including us, and the industries in which we operate, face significant compliance and operational risks and uncertainties. For example, on July 24, 2021, Chinese state media, including Xinhua News Agency and China Central Television, announced a broad set of reforms targeting private education companies providing after-school tutoring services and prohibiting foreign investments in institutions providing such after-school tutoring services. As a result, the market value of certain U.S. listed companies with China-based operations in the affected sectors declined substantially. We are not aware of any similar regulations that may be adopted to significantly curtail our business operations. However, if such other adverse regulations or policies are adopted in China, the potential Joint Venture may be materially and adversely affected, which may significantly disrupt our operations and adversely affect our business. In the event any of the foregoing were to occur, we and the potential Joint Venture will take any and all actions to remain in compliance with any such regulations or policies.

**We may be subject to anti-monopoly concerns as a result of our doing business in China.**

Article 3 of Anti-Monopoly Law of the People's Republic of China prohibits "monopolistic practices," which include: a) the conclusion of monopoly agreements between operators; b) the abuse of dominant market position by operators; c) concentration of undertakings which has or may have the effect of eliminating or restricting market competition. Also, according to Article 19, the operator(s) will be assumed to have a dominant market position if it has following situation: a) an operator has 50% or higher market share in a relevant market; b) two operators have 66% or higher market share in a relevant market; c) three operators have 75% or higher market share in a relevant market. We believe we have not conducted any monopolistic practices in China, and that recent statements and regulatory actions by the Chinese government do not impact our ability to conduct business, accept foreign investments, create the potential Joint Venture with Wider or list on a U.S. or other foreign stock exchange. However, there can be no assurance that regulators in China will not promulgate new laws and regulations or adopt new series of regulatory actions which may require us or the potential Joint Venture to meet new requirements on the issues mentioned above.

**We may be subject to regulatory and other risks if we were to operate Variable Interest Entities in China**

In July 2021, the Chinese government provided new guidance on China-based companies raising capital outside of China, including through arrangements called variable interest entities ("VIEs"). In light of such developments, the SEC has imposed enhanced disclosure requirements on China-based companies seeking to register securities with the SEC. Although we do not have a VIE structure, due to our potential Joint Venture, any future Chinese, U.S. or other rules and regulations that place restrictions on capital raising or other activities may adversely affect our business and results of operations. If the business environment in China deteriorates from the perspective of domestic or international investment, or if relations between China and the United States or other governments deteriorate, the Chinese government may intervene with our operations and our business in China and United States, as well as the market price of our securities, may also be adversely affected.

Our business does not appear to be within the targeted areas of concern by the Chinese government. However, because of our intended potential Joint Venture, there is a risk that the Chinese government may in the future seek to affect operations of any company with any level of operations in Hong Kong or China, including its ability to offer securities to investors, list its securities on a U.S. or other foreign exchange, conduct its business or accept foreign investment. Substantial uncertainties and restrictions with respect to the political and economic policies of the PRC government and PRC laws and regulations could have a significant impact upon the business that we may be able to conduct in the PRC and accordingly on the results of our operations and financial condition. If any or all of the foregoing were to occur, it could, in turn, result in a material change in the Company's operations and/or the value of its common stock and/or significantly limit or completely hinder its ability to offer or continue to offer securities to investors and cause the value of such securities to significantly decline or be worthless. Furthermore, in the event any of the foregoing were to occur or to be interpreted differently, we and the potential Joint Venture will take any and all actions to remain in compliance with any such laws or regulations or detailed implementations and interpretations thereof.

**If we are unable to obtain and maintain patent protection for our technologies and products, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technologies and products similar or identical to ours, and our ability to successfully commercialize our technologies and products may be impaired.**

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our products. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our technologies and products. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage that we may have, which could harm our business and ability to achieve profitability. To protect our proprietary positions, we file patent applications in the United States and abroad related to our novel technologies and products that are important to our business. The patent application and prosecution processes are expensive and time-consuming. We and our current licensees, or any future licensors and licensees may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We or our current licensees, or any future licensors or licensees may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Therefore, these and any of our

patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If our current licensees, or any future licensors or licensees, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised and we might not be able to prevent third parties from making, using and selling competing products. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Any of these outcomes could impair our ability to prevent competition from third parties.

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Furthermore, recent changes in patent laws in the United States, including the America Invents Act of 2011, may affect the scope, strength and enforceability of our patent rights or the nature of proceedings that may be brought by us related to our patent rights.

We may not be aware of all third-party intellectual property rights potentially relating to our current and future our products. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until eighteen months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Similarly, should we own any patents or patent applications in the future, we may not be certain that we were the first to file for patent protection for the inventions claimed in such patents or patent applications. As a result, the issuance, scope, validity and commercial value of our patent rights cannot be predicted with any certainty. Moreover, we may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, re-examination, *inter partes* review or interference proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

Our pending and future patent applications may not result in patents being issued that protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection against competing products or processes sufficient to achieve our business objectives, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. Alternatively, our competitors may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid and/or unenforceable.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technologies and products, or limit the duration of the patent protection of our technologies and products. In addition, given the amount of time required for the development, testing and regulatory review of new products, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

**We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.**

Competitors may infringe our issued patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, trademarks, copyrights or other intellectual property. In addition, in a patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patents do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

In any infringement litigation, any award of monetary damages we receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating or successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a negative impact on our ability to compete in the marketplace.

**Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could significantly harm our business.**

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our products and use our proprietary technologies without infringing the intellectual property and other proprietary rights of third parties.

There is potential for a substantial amount of intellectual property litigation in our industry, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our technology or products, including interference proceedings before the USPTO. Intellectual property disputes arise in a number of areas including with respect to patents, use of other proprietary rights and the contractual terms of license arrangements. Third parties may assert claims against us based on existing or future intellectual property rights. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance.

If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate.

However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our products or force us to cease some of our business operations. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative effect on our business.

**If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.**

In addition to seeking patent and trademark protection for our products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Moreover, our competitors may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors could purchase our products and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

**We may not be able to protect our intellectual property rights throughout the world.**

Filing, prosecuting and defending patents on products in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. In some cases, we may not be able to obtain patent protection for certain licensed technology outside the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, even in jurisdictions where we do pursue patent protection or from selling or importing products made using our inventions in and into the United States or other jurisdictions.

Competitors may use our technologies in jurisdictions where we have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and preclinical programs and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents, if pursued and obtained, or marketing of competing products in violation of our proprietary rights generally.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us.

We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

#### *Risks Related to Regulatory Approval of Our Products and Other Legal Compliance Matters*

**Even if we complete the necessary preclinical studies and clinical trials, the regulatory approval process is expensive, time-consuming and uncertain and may prevent us or any future collaborators from obtaining approvals for the commercialization of some or all of our products. As a result, we cannot predict when or if, and in which territories, we, or any future collaborators, will obtain marketing approval to commercialize a product candidate.**

Our products and the activities associated with their development and commercialization, including their design, research, testing, manufacture, safety, efficacy, quality control, recordkeeping, labelling, packaging, storage, approval, advertising, promotion, sale, distribution, import, export and reporting of safety and other post-market information, are subject to comprehensive regulation by the FDA and other foreign regulatory agencies including the NMPA. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. As a result of the FDA reclassification ruling in December 2019, which impacted the classification of our devices, we had to suspend marketing of our first-Generation medical device for the treatment of anxiety and insomnia. We are presently communicating with the FDA with regard to amending our previous 510(k) Application for the treatment of anxiety and insomnia with our Gen-1 device in accordance with the FDA ruling. Our Gen - 2 medical device has completed development and is in the prototype stage of manufacturing and testing. Securing marketing approval from the FDA in the United States requires the submission of extensive testing and clinical data to regulatory authorities for each therapeutic indication to establish the candidate's safety and efficacy. Securing marketing approval also requires the

submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our products may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

In addition, changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical, or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of our products, the commercial prospects for our products may be harmed and our ability to generate revenues will be impaired.

**Failure to obtain marketing approval in foreign jurisdictions would prevent our products from being marketed in these territories. Any approval we are granted for our products in the United States would not assure approval of our products in foreign jurisdictions.**

To market and sell our products in China and any other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain approval from the FDA in the United States. The regulatory approval process outside the United States generally includes all the risks associated with obtaining approval from the FDA. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, failure to obtain approval in one jurisdiction may impact our ability to obtain approval elsewhere. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market.

**The U.S. FDA, Chinese National Medical Products Administration and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.**

We have chosen, and may continue to choose, to conduct international clinical trials. The acceptance of study data by the U.S. FDA, Chinese National Medical Products Administration (NMPA) or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (1) the data are applicable to the United States population and United States medical practice; (2) the trials are performed by clinical investigators of recognized competence and pursuant to Current Good Clinical Practice requirements; and (3) the FDA is able to validate the data through an on-site inspection or other appropriate means. The FDA may accept the use of some foreign data to support a marketing approval if the clinical trial meets certain requirements. Additionally, the FDA's clinical trial requirements, including the adequacy of the subject population studied and statistical powering, must be met. Furthermore, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, NMPA or any applicable foreign regulatory authority will accept data from trials conducted outside of its respective jurisdiction. If the FDA, NMPA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval for commercialization in the applicable jurisdiction.

**Even if we obtain marketing approvals for our products, the terms of approvals and ongoing regulation of our products may limit how we manufacture and market our products and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue.**

Even if marketing approval of a product candidate is granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation, including the potential requirements to implement a risk evaluation and mitigation strategy or to conduct costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. We must also comply with requirements concerning advertising and promotion for any of our products for which we obtain marketing approval. Promotional communications are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labelling. Thus, we will not be able to promote any products we develop for indications or uses for which they are not approved. In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements including ensuring quality control and manufacturing procedures, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We and our contract manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance.

**Our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.**

We are exposed to the risk of employee fraud or other misconduct or failure to comply with applicable regulatory requirements. Misconduct by employees and independent contractors, such as principal investigators, consultants, commercial partners and vendors, could include failures to comply with regulations of the FDA and other comparable regulatory authorities, to provide accurate information to such regulators, to comply with manufacturing standards we have established, to comply with healthcare fraud and abuse laws, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of business activities, including, but not limited to, research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee and independent contractor misconduct could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. In addition, federal procurement laws impose substantial penalties for misconduct in connection with government contracts and require certain contractors to maintain a code of business ethics and conduct. It is not always possible to identify and deter employee and independent contractor misconduct, and any precautions we take to detect and prevent improper activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate.

**Our current and future relationships with healthcare professionals, principal investigators, consultants, customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, physician payment transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to penalties.**

Healthcare providers, physicians, clinicians, and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, that may constrain the business or financial arrangements and relationships through which we research, sell, market and distribute any products for which we obtain marketing approval. In addition, we may be subject to physician payment transparency laws and patient privacy and security regulation by the federal government and by the states and foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws that may affect our ability to operate include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under federal and state healthcare programs such as Medicare and Medicaid;
- federal civil and criminal false claims laws, including the federal False Claims Act, which impose criminal and civil penalties, including through civil whistleblower or *qui tam* actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the civil monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of whether the payor is public or private, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose obligations on "covered entities," including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective "business associates" that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act, created under Section 6002 of Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, and its implementing regulations, created annual reporting requirements for manufacturers of products, devices, biologicals and medical supplies for certain payments and "transfers of value" provided to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

- analogous state and foreign laws, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require companies to comply with voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or to adopt compliance programs as prescribed by state laws and regulations, or that otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

Further, the ACA, among other things, amended the intent requirement of the federal Anti-Kickback Statute and certain criminal statutes governing healthcare fraud. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the ACA provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Efforts to ensure that our future business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and pursue our strategy. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including future collaborators, are found not to comply with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also affect our business.

**Recently enacted and future legislation may increase the difficulty and cost for us and our collaborators to obtain marketing approval of and commercialize our products and affect the prices we may obtain.**

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent, alter or delay marketing approval of our existing or future products, restrict or regulate post-approval activities and affect our ability to profitably sell any products for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. For example, the ACA, which was enacted in the United States in March 2010, includes measures to change health care delivery, decrease the number of individuals without insurance, ensure access to certain basic health care services, and contain the rising cost of care. The healthcare reform movement, including the enactment of the ACA, has significantly changed health care financing by both governmental and private insurers in the United States. With respect to pharmaceutical manufacturers, the ACA increased the number of individuals with access to health care coverage, but it simultaneously imposed, among other things, increased liability for rebates and discounts owed to certain entities and government health care programs, and new transparency reporting requirements under the Physician Payments Sunshine Act. For a detailed discussion of the ACA's provisions of importance to the pharmaceutical industry, as well as a description of reform legislation passed subsequent to the ACA, see the section titled "Business — Government Regulation — Healthcare Reform Efforts."

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, as well as efforts to repeal or replace certain aspects of the ACA. We continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business. It is uncertain the extent to which any such changes may impact our business or financial condition.

In addition to the ACA, other federal health reform measures have been proposed and adopted in the United States. For example, legislation has been enacted to reduce the level of reimbursement paid to providers under the Medicare program over time, as well as phase in alternative payment models for provider services under the Medicare program with the goal of incentivizing the attainment of pre-defined quality measures. As these measures are not fully in effect, and since the U.S. Congress could intervene to prevent their full implementation, at this time, it is unclear how payment reductions or the introduction of the quality payment program will impact overall physician reimbursement under the Medicare program. It is also unclear if changes in Medicare payments to providers would impact such providers' willingness to prescribe and administer our existing or future products, if approved. Further, there has been heightened governmental scrutiny over the manner in which companies set prices for their marketed products. For example, there have been several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, review the relationship between pricing and patient programs, and reform government reimbursement methodologies for products.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our products, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labelling and post-marketing testing and other requirements.

Various new healthcare reform proposals are emerging at the federal and state level. It is also possible that additional governmental action will be taken in response to the COVID-19 pandemic. Any new federal and state healthcare initiatives that may be adopted could limit the amounts that federal and state governments will pay for healthcare products and services, and could harm our business, financial condition and results of operations.

**Our business activities may be subject to the U.S. Foreign Corrupt Practices Act, or the FCPA, and similar anti-bribery and anti-corruption laws of other countries in which we operate, as well as U.S. and certain foreign export controls, trade sanctions and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.**

If we further expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits companies and their employees and third-party intermediaries from offering, promising, giving or authorizing the provision of anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, hospitals owned and operated by the government and doctors and other hospital employees would be considered foreign officials under the FCPA. Recently the SEC and DOJ have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all our employees, agents or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, disgorgement and other sanctions and remedial measures and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business, prospects, operating results and financial condition.

In addition, our products and technology may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our products and technology, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons or products targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to, existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell access to our products would likely adversely affect our business.

#### *Risks Related to Ownership of Our Common Stock and Warrants and Our Status as a Public Company*

**An active trading market for our common stock and warrants may not develop and you may not be able to resell your shares at or above the initial offering price, if at all.**

We completed our initial public offering in September 2022. In our initial public offering, we issued shares of common stock and common stock warrants. These securities are listed for trading on the Nasdaq Stock Market. The timing of our initial public offering and the subsequent period of time until the filing of this Form 10-K has coincided with a downturn in the U.S. economy and the capital markets. The downturn has negatively affected trading in securities generally, and our securities in particular. Our securities have not traded at the same prices as they were issued in our initial public offering. Generally, there is a limited trading market for our shares of common stock and warrants. There can be no assurance that there will be an increase in the trading of our securities. As a result, investors may be required to hold our securities for a longer period than originally contemplated.

**Warrants are speculative in nature.**

Our warrants do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of our common stock at a fixed price for a limited period of time. Specifically, commencing on the date of issuance, holders of the warrants may exercise their right to acquire the common stock and pay an exercise price of \$4.15 per share prior to three (3) years from the date of issuance, after which date any unexercised warrants will expire and have no further value.

**The warrants may not have any value.**

The warrants have an exercise term which expires three (3) years from the date of the closing of our IPO (September 16, 2022) at an initial exercise price equal to \$4.15 per share. There can be no assurance that the market price of our shares of common stock will ever equal or exceed the exercise price of the warrants. In the event that the stock price of our shares of common stock does not exceed the exercise price of the warrants during the period when the warrants are exercisable, the warrants may not have any value.

**We may redeem your unexpired warrants prior to their exercise at a time that is disadvantageous to you, thereby making your warrants worthless.**



We have the ability to redeem outstanding warrants at any time after they become exercisable and prior to their expiration, at a price of \$0.01 per warrant, provided that the last reported sales price of our shares equal or exceed \$12.45 per share (as adjusted for share splits, share capitalizations, rights issuances, subdivisions, reorganizations, recapitalizations and the like) for any 20 trading days within a 30 trading-day period ending on the third trading day prior to the date we send the notice of redemption to the warrant holders. If and when the warrants become redeemable by us, we may not exercise our redemption right if the issuance of shares upon exercise of the warrants is not exempt from registration or qualification under applicable state blue sky laws or we are unable to effect such registration or qualification. We will use our best efforts to register or qualify such shares under the blue sky laws of the state of residence in those states in which the warrants were offered by us in our recently completed public offering. To date, however, we have not filed any registration statement to provide for the exercise and free trading of the underlying shares of common stock. Redemption of the outstanding warrants could force you (i) to exercise your warrants and pay the exercise price therefor at a time when it may be disadvantageous for you to do so, (ii) to sell your warrants at the then-current market price when you might otherwise wish to hold your warrants or (iii) to accept the nominal redemption price which, at the time the outstanding warrants are called for redemption, is likely to be substantially less than the market value of your warrants.

**Holders of the Warrants will have no rights as a common stockholder until they acquire our common stock.**

Until holders of the warrants acquire shares of our common stock upon exercise of the warrants, the holders will have no rights with respect to shares of our common stock issuable upon exercise of the warrants. Upon exercise of the warrants, the holder will be entitled to exercise the rights of a common stockholder as to the security exercised only as to matters for which the record date occurs after the exercise.

**Our Warrant Agreement designates the courts of the State of New York or the United States District Court for the Southern District of New York as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by holders of our Warrants, which could limit the ability of Warrant holders to obtain a favorable judicial forum for disputes with our Company.**

Our Warrant Agreement provides that, subject to applicable law, (i) any action, proceeding or claim against us arising out of or relating in any way to the Warrant Agreement, including under the Securities Act, will be brought and enforced in the courts of the State of New York or the United States District Court for the Southern District of New York, and (ii) that we irrevocably submit to such jurisdiction, which jurisdiction shall be the exclusive forum for any such action, proceeding or claim. We will waive any objection to such exclusive jurisdiction and that such courts represent an inconvenient forum.

Notwithstanding the foregoing, these provisions of the Warrant Agreement will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal district courts of the United States of America are the sole and exclusive forum. Any person or entity purchasing or otherwise acquiring any interest in any of our Warrants shall be deemed to have notice of and to have consented to the forum provisions in our Warrant Agreement.

If any action, the subject matter of which is within the scope of the forum provisions of the Warrant Agreement, is filed in a court other than courts of the State of New York or the United States District Court for the Southern District of New York (a "foreign action") in the name of any holder of our Warrants, such holder shall be deemed to have consented to: (x) the personal jurisdiction of the state and federal courts located in the State of New York in connection with any action brought in any such court to enforce the forum provisions (an "enforcement action"), and (y) having service of process made upon such Warrant holder in any such enforcement action by service upon such Warrant holder's counsel in the foreign action as agent for such Warrant holder.

This choice-of-forum provision may limit a warrant holder's ability to bring a claim in a judicial forum that it finds favorable for disputes with our Company, which may discourage such lawsuits. Alternatively, if a court were to find this provision of our Warrant Agreement inapplicable or unenforceable with respect to one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could materially and adversely affect our business, financial condition and results of operations and result in a diversion of the time and resources of our management and Board of Directors.

**The trading price of our common stock and warrants may be volatile, and you could lose all or part of your investment.**

The trading price of our common stock and warrants is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. The stock market in general and the market for companies in our industry in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their shares or warrants at or above the price paid for the units. In addition to the factors discussed in these "Risk Factors" sections, these factors include:

- the commencement, enrollment or results of our planned and future clinical trials;
- the loss of any of our key scientific or management personnel;
- regulatory or legal developments in the United States, China and other countries;
- the success of competitive products or technologies;
- adverse actions taken by regulatory agencies with respect to our clinical trials or manufacturers;

- changes or developments in laws or regulations applicable to our products and preclinical program;
- changes to our relationships with collaborators, manufacturers or suppliers;
- the results of our testing and clinical trials;
- unanticipated safety concerns;
- announcements concerning our competitors or our industry in general;
- actual or anticipated fluctuations in our operating results;
- changes in financial estimates or recommendations by securities analysts;

- potential acquisitions;
- the results of our efforts to discover, develop, acquire or in-license additional products;
- the trading volume of our securities on Nasdaq;
- sales of our common stock by us, our executive officers and directors or our stockholders or the anticipation that such sales may occur in the future;
- general economic, political and market conditions and overall fluctuations in the financial markets in the United States or China;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in our industry; and
- investors' general perception of us and our business.

These and other market and industry factors may cause the market price and demand for our common stock and warrants to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from selling their shares of our common stock and warrants at or above the price paid for the units or the exercise price of the warrants and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general, and companies in our industry in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Some companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time-consuming and could divert our management's attention and our resources. Furthermore, during litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our common stock.

**If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.**

The trading market for our common stock and warrants will be influenced by the research and reports that equity research analysts publish about us and our business. We do not currently have and may never obtain research coverage by equity research analysts. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock and warrants. In the event we do have equity research analyst coverage, we will not have any control over the analysts, or the content and opinions included in their reports. The price of our shares and warrants could decline if one or more equity research analysts downgrade our shares or issue other unfavorable commentary or research about us. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our shares could decrease, which in turn could cause the trading price or trading volume of our common stock and warrants to decline.

**A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.**

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly.

Upon completion of our public offering in September 2022, we had outstanding 7,279,961 shares of our common stock. Of these shares, the 2,315,000 shares sold in our public offering are freely tradable and 1,528,271 pre offering shares were eligible for sale in the public market immediately upon the effectiveness of the registration statement for the offering. An additional 3,362,567 shares of our common stock (including an aggregate of 1,704,438 shares held by officers, directors and affiliates) will be available for sale in the public market beginning 180 days after the date of public offering (March 20, 2023) following the expiration of lock-up agreements between our stockholders and the underwriters, subject in certain circumstances to the volume, manner of sale and other limitations under Rule 144 and Rule 701. The representatives of the underwriters may release those stockholders subject to a lock-up agreement from their lock-up agreements with the underwriters at any time, which would allow for earlier sales of shares in the public market.

**There can be no assurances that our shares and warrants will not be subject to potential delisting from the Nasdaq Stock Market if we do not continue to maintain the listing requirements of Nasdaq, which could negatively impact the price and value of our securities and your ability to sell them.**

Our shares of our common stock and warrants are listed on the Capital Market tier of the Nasdaq Stock Market, or Nasdaq, under the symbols "NXL" and "NXLIW". Nasdaq has rules for continued listing, including, without limitation, minimum market capitalization, minimum stockholders' equity and other requirements. Failure to maintain our listing (i.e., being de-listed from Nasdaq) could result in significant consequences for us and our security holders including:

- making it more difficult for holders to sell our common stock or warrants and more difficult to obtain accurate price quotations for such securities;
- resulting in an adverse effect on the price of our common stock and warrants;
- adversely our ability to issue additional securities for financing or other purposes, or otherwise to arrange for any financing we may need in the future;
- resulting in determination that our common stock is a "penny stock," which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our common stock; and
- reducing the amount of news and analyst coverage of our company and our securities.

**Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions and matters submitted to stockholders for approval.**

Our executive officers, directors and current beneficial owners of 5% or more of our common stock and their respective affiliates, in the aggregate, beneficially own approximately 23.38% of our outstanding common stock, based on the number of shares of our common stock outstanding as of March 22, 2023. As a result, these persons, acting together, would be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors, any merger, consolidation or sale of all or substantially all of our assets or other significant corporate transactions. In addition, these persons, acting together, may have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership may harm the market price of our common stock by:

- delaying, deferring or preventing a change in control;

- entrenching our management and/or the board of directors;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

In addition, some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the price at which shares were sold in our public offering and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders.

**Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.**

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws that became effective on December 1, 2021 (as amended August 11, 2022) may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings; and
- require the approval of the holders of at least 66.66% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws or remove a director.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired more than 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

**Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America are the exclusive forums for substantially all disputes between us and our stockholders, including claims under the Securities Act and the Exchange Act, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.**

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us or any of our directors, officers, employees or agents arising under the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws;
- any action or proceeding to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws; and
- any action asserting a claim against us or any of our directors, officers, employees or agents that is governed by the internal-affairs doctrine.

Our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act and the Exchange Act.

These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions. We note that there is uncertainty as to whether a court would enforce such exclusive-forum provision and that provision may result in increased costs for investors to bring a claim. We also note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder, and that Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.

**We are an "emerging growth company" and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock and warrants may be less attractive to investors.**

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, we do not intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act;

- not being required to comply with any requirements that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the consolidated financial statements;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our common stock or warrants less attractive because we will rely on these exemptions. If some investors find our common stock or warrants less attractive as a result, there may be a less active trading market for our common stock and warrants and the trading prices for our securities may be more volatile. We may take advantage of these exemptions until the last day of our fiscal year following the fifth anniversary of the completion of our IPO. However, if any of the following events occur prior to the end of such five-year period, (i) our annual gross revenue exceeds \$1.07 billion, (ii) we issue more than \$1.0 billion of non-convertible debt in any three-year period or (iii) we become a "large accelerated filer;" (as defined in Rule 12b-2 under the Exchange Act), we will cease to be an emerging growth company prior to the end of such five-year period. We will be deemed to be a "large accelerated filer" at such time that we (a) have an aggregate worldwide market value of common equity securities held by non-affiliates of \$700 million or more as of the last business day of our most recently completed second fiscal quarter, (b) have been required to file annual and quarterly reports under the Exchange Act, for a period of at least twelve months and (c) have filed at least one annual report pursuant to the Exchange Act. Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements including reduced disclosure obligations regarding executive compensation in this Form 10-K and our other periodic reports and proxy statements.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected to avail ourselves 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 emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

**If we fail to maintain proper and effective internal controls, our ability to produce accurate consolidated financial statements on a timely basis could be impaired.**

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, the Sarbanes-Oxley Act and the rules and regulations of The Nasdaq Capital Market, or Nasdaq. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. Beginning with our second annual report following our initial public offering (December 2024), we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting in our Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. This will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. We have never been required to test our internal controls within a specified period, and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

We identified control deficiencies in the design and operation of our internal control over financial reporting that constituted a material weakness, as further described in Item 9A of this Annual Report ("Controls and Procedures"). A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our consolidated financial statements will not be prevented or detected on a timely basis. Our material weakness related to the following control deficiencies:

- Lack of sufficient resources necessary to provide adequate segregation of duties related to the preparation and review of financial information used in financial reporting and review of controls over the financial reporting process, including documentation of review/approval of journal entries and reconciliations; and
- Insufficient IT controls which are effectively designed and implemented, specifically related to user/superuser access to the Company's financial reporting system.

Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our common stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities.

**Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment.**

You should not rely on an investment in our common stock to provide dividend income. We have never declared or paid a dividend on our common stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, on our common stock will be your sole source of gains for the foreseeable future. Investors seeking cash dividends should not purchase our common stock.

**Tax authorities may disagree with our positions and conclusions regarding certain tax positions, resulting in unanticipated costs, taxes or non-realization of expected benefits.**

A tax authority may disagree with tax positions that we have taken, which could result in increased tax liabilities. For example, the Internal Revenue Service or another tax authority could challenge our allocation of income by tax jurisdiction and the amounts paid between our affiliated companies pursuant to our intercompany arrangements and transfer pricing policies, including amounts paid with respect to our intellectual property development. Similarly, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a "permanent establishment" under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. The foregoing are only selected examples of potential challenges, and other tax positions we have taken or may take in the future could become the subject of disputes with one or more tax authorities. A tax authority may take the position that material income tax liabilities, interest and penalties are payable by us, in which case, we expect that we might contest such assessment. Contesting such an assessment may be lengthy and costly and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate, where applicable.

**We will incur significantly increased costs as a result of operating as a company whose common stock is publicly traded in the United States, and our management will be required to devote substantial time to new compliance initiatives.**

As a public company in the United States, we will continue to incur significant legal, accounting and other expenses that we did not incur previously. These expenses will likely be even more significant after we no longer qualify as an emerging growth company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on public companies in the United States, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our senior management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified senior management personnel or members for our board of directors.

However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404, we will be required to furnish a report by our senior management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To prepare for eventual compliance with Section 404, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our consolidated financial statements.

## ITEM 1B UNRESOLVED STAFF COMMENTS

None

## ITEM 2. PROPERTIES

Our principle executive office is located at 1776 Yorktown, Suite 550, Houston, Texas 77056. Under ASC 842 "Leases", we have two separate sub-leases totalling approximately 4,000 square feet of office space under operating leases. Our lease payments totalled approximately \$48,000 in 2021. Management and supporting staff are hosted at this location. Our lease payments for fiscal year 2022 were \$54,000. Our lease costs for 2023 will also be \$54,000 for the year. The sub-leases are due to expire in 2024. We sublease our space from an entity controlled by our Chief Executive Officer. We do not have any increase from the primary lease payments for the sub-lease arrangements.

We do not own or operate manufacturing facilities for the production of any of our products, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We believe our current premises are sufficient for our needs at this time and for the foreseeable future.

## ITEM 3 LEGAL PROCEEDINGS

There are no material pending legal proceedings in which the Company or any of its subsidiaries is a party or in which any director, officer or affiliate of the Company, any owner of record or beneficially of more than 5% of any class of its voting securities, or security holder is a party adverse to us or has a material interest adverse to the Company other than the following:

*Sarah Veltz v. Nexalin Technology, Inc. et al.*

Plaintiff, Sarah Veltz, filed a lawsuit in this matter on January 20, 2021 in Orange County Superior Court (Case No. 30-2021-01180164-CU-WT-CJC) (the "Complaint") naming the Company and others as defendants. In her Complaint, Plaintiff contends that she was employed by defendants, including Nexalin, and has not been paid all wages, including overtime wages and other benefits allegedly due her. Plaintiff also contends that, during her employment, she was subjected to sexual harassment by the Company's then Chief Executive Officer. Plaintiff seeks both compensatory and punitive damages. On March 12, 2021, the Company filed its answer to the Complaint. Although the parties are seeking mediation, the court has set a jury trial in this matter for April 24, 2023. Management's intent is to contest the allegations vigorously and, as of the date of this report, is unable to provide an evaluation of the potential outcome of the litigation within the probable or remote range or to provide an estimate of the amount of or a range of potential loss that might be incurred by the Company.

*Employment Development Department*

The Company is currently engaged in settlement discussions with the Employment Development Department (EDD) of the state of California. This matter involves issues related to our previous management's classification of certain work provided to or on behalf of the Company's business as contract labor instead of employee labor. The total amount involved is approximately \$300,000. Management has petitioned for reassessment and believe the hired workers at issue were indeed actual contractors and not employees. We have no business in California other than one part time and one full time worker residing in California. An initial hearing before an EDD magistrate was held on April 15, 2022. A second hearing was held in June of 2022. We are now in negotiations with the EDD for a final settlement. The Company believes its potential exposure to be approximately \$300,000 and, as such, has accrued this amount on the audited consolidated balance sheets at December 31, 2022 and 2021 and believes it has adequately accrued for this matter.

*Demand Letter from The University of Arizona*

On December 8, 2022, the Company received a demand letter from the University of Arizona seeking payment of \$111,094 purportedly due on an Investigator Initiated Cooperative Study Agreement, dated as of September 25, 2017 (the "2017 Study") The Company believes that the 2017 Study was not completed and no payment was due. In fact, for a number of months prior to receipt of the demand letter, the Company had had discussions with the person at the University of Arizona who were to conduct the 2017 Study concerning updating the 2017 Study and completing an updated study and related work. After receipt of the demand letter, the Company has had discussions with the University of Arizona concerning resuming an updated study and receipt of credit for some or all the monies claimed to be due for the 2017 Study. Such discussions are ongoing, and no resolution has been reached but the Company hopes to achieve a consensual resolution. We cannot guarantee that a mutually amicable resolution will be reached by the parties.

## ITEM 4 MINE SAFETY

Not Applicable

## ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

### Principal Market

Our common stock is currently traded on The Nasdaq Capital Market under the symbol "NXL." Our common stock warrants are listed for trading on The Nasdaq Capital Market under the symbol "NXLW"

### Equity Holders

As of March 22, 2023, the number of shareholders of our common stock of record was approximately 900 persons and the last reported closing price per share of our common stock on such date was \$1.09. The number of stockholders of record is not representative of the number of beneficial stockholders due to the fact that many shares are held by depositories, brokers, or nominees.

### Dividends

We have not declared or paid any cash dividends on its common stock since inception. We do not intend to pay any cash dividends at this time or in the foreseeable future.

### Recent Sales of Unregistered Securities

We completed our initial public offering on September 16, 2022.

We issued an aggregate of 6,601 restricted securities to a consultant during the fourth quarter (October 1, 2022 to December 31, 2022). These shares were issued pursuant to agreements which were in place prior to our initial public offering and represented payment for services. All of such shares were issued pursuant to an exemption from registration under the Securities Act of 1933 as amended including Regulation D promulgated thereunder and are restricted securities which may not be sold without registration or only pursuant to an exemption therefrom such as Rule 144.

### Repurchase of Equity Securities

None.

### Securities Authorized for Issuance under Equity Compensation Plans

We did not have any equity compensation plan in effect during the year ended December 31, 2022 and we do not have any equity compensation plan as of the date of filing of this Report on Form 10-K. We expect to seek stockholder approval of a stock based equity plan in calendar year 2023.

See Item 11. "Executive Compensation" for a discussion of certain stock related compensation agreements with certain of our executive officers.

## ITEM 6 [RESERVED]

## ITEM 7 MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

### Special Note Regarding Forward-Looking Statements

*You should read the following discussion and analysis of financial condition and operating results together with our financial statements and the related notes and other financial information included elsewhere in this annual report on Form 10-K. References in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" to "us," "we," "our," and similar terms refer to Nexalin Technology, Inc. This discussion contains forward-looking statements as that term is defined within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which are subject to the "safe harbor" created by those sections. The events described in forward-looking statements contained in this discussion may not occur. Generally, these statements relate to business plans or strategies, projected or anticipated benefits or other consequences of our plans or strategies, projected or anticipated benefits from acquisitions that may be made by us, or projections involving anticipated revenues, earnings or other aspects of our operating results. The words "may," "will," "expect," "believe," "anticipate," "project," "plan," "intend," "estimate," and "continue," and their opposites and similar expressions, are intended to identify forward-looking statements. We caution you that these statements are not guarantees of future performance or events and are subject to a number of uncertainties, risks and other influences, many of which are beyond our control, which may influence the accuracy of the statements and the projections upon which the statements are based. Reference is made to "Risk Factors" in this annual report on Form 10-K. Our actual results may differ materially from those anticipated in these forward-looking statements. For convenience of presentation some of the numbers have been rounded in the text below.*

### Overview

We design and develop innovative neurostimulation products to uniquely and effectively help combat the ongoing global mental health epidemic. We developed an easy-to-administer medical device — referred to as Generation 1 or Gen-1 — that utilizes bioelectronic medical technology to treat anxiety and insomnia, without the need for drugs or psychotherapy. Our original Gen-1 devices are cranial electrotherapy stimulation (CES) devices that emit waveform at 4 milliamps during treatment and are presently classified by the U.S. Food and Drug Administration ("FDA") as a Class II device.

Medical professionals in the United States have utilized the Gen-1 device to administer to patients in clinical settings. While the Gen-1 device had been cleared by the FDA to treat depression, anxiety, and insomnia, three prevalent and serious diseases, because of the FDA's December 2019 reclassification of CES devices, the Gen-1 device was reclassified as a Class II device for the treatment of anxiety and insomnia. We are required to file a new application under Section 510(k) of the Federal Food, Drug and Cosmetic Act ("510(k) Application") to be approved by the FDA for the sales and marketing of our devices for the treatment of anxiety and insomnia. In the FDA's December 2019 reclassification ruling, the treatment of depression with our device will require a Class III certification and require a new PMA (premarket approval) application to demonstrate safety and effectiveness.

While we continue providing services to medical professionals to support patients' use of the Gen-1 devices which were in operation prior to December 2019, we are not making new sales or new marketing efforts of Gen-1 devices in the United States. We continue to derive revenue from devices which we sold or leased prior to the FDA's December 2019 reclassification announcements. This revenue consists of monthly licensing fees and payments for the sale of electrodes and patient cables. We have suspended marketing efforts for new sales of devices related to the Gen-1 device for treatment of anxiety and insomnia in the United States until the Nexalin regulatory team makes a decision on a new 510(k) application at 4 milliamps based on FDA comments expected to be received in April 2023. Our regulatory team continues to inform the FDA of the suspension of the marketing and sale of the Gen-1 products to new providers. We are analyzing whether to proceed with an amended application with the FDA for Gen-1 devices for the treatment of insomnia and anxiety.

We have designed and developed a new advanced waveform technology to be emitted at 15 milliamps through new and improved medical devices referred to as Generation 2 or Gen-2 and Generation 3 or Gen-3. Gen-2 is a clinical use device with a modern enclosure to emit the new 15 milliamp advanced waveform. Gen-3 is a new patient headset that will be prescribed by licensed medical professionals in a virtual clinic setting similar to existing Tele-health platforms. The Nexalin research team believes that the new 15 milliamp Gen-2 and Gen-3 devices can penetrate deeper into the brain and stimulate associated structures of mental illness, which we believe will generate enhanced patient response without any risk or unpleasant side effects. The Nexalin regulatory team has made a strategic decision to develop strategies for pilot trials in various mental health disease states. In addition, a new PMA application in the United States is in development for the treatment of depression utilizing both Gen-2 and Gen-3. The new Gen-3 device is also scheduled for additional pilot trials for anxiety and insomnia in the United States and China beginning in the third quarter of 2023. Preliminary data provided by the University of California San Diego supports the safety of utilizing our 15 milliamp waveform technology. However, the determination of safety and efficacy of medical devices in the United States is subject to clearance by the FDA.

Additionally, we are currently designing clinical trial strategies for the use of Gen-3 for the treatment of substance use disorders including opiate, cocaine, and alcohol abuse. Recently the Gen-2 device was tested in pilot trials in China for the treatment of Alzheimer's disease and dementia. Continued pilot testing for Alzheimer's and dementia is planned in China in 2023.

In part due to increasing incidence attributed to the devastating impacts of the COVID-19 pandemic, mental health and cognitive disorders are widespread across the globe and cause substantial health, social and economic losses, and hardships accordingly. Our focus is on the continued development of our innovative bioelectronic medical technologies and rapid regulatory approval. We intend to help reverse these losses, and hardships of these losses, by safely and effectively treating various mental health disorders associated with post Covid and long Covid mental disease states.

All our products are non-invasive, safe, undetectable to the human body and can provide relief to those afflicted with mental health issues without adverse side effects. We have a proprietary design that eliminates voltage while stabilizing currents, electromagnetic fields, and various frequencies — referred to collectively as waveform - particularly our proprietary, 15 milliamp patented symmetrical waveform. Our devices generate a high frequency carrier wave that is charge balanced. It is applied to the brain with an array of electrodes on the forehead and behind each ear at the mastoid. The features of this proprietary waveform and the array of electrodes allow the application of the waveform to the entire brain rather than a small, targeted area of the brain. To ensure deeper penetration into the brain, we have eliminated the voltage from the waveform which allows the increase of the power from < 4 mAmps to 15 mAmps, more than a 400% increase without incurring any patient discomfort, risk, or adverse side effects. By increasing the power, our waveform can penetrate deeper into the brain and stimulate deep mid-brain structures associated with mental illness. Our research and clinical teams believe that a more powerful waveform will create a stronger response in the brain. A stronger response creates a higher level of efficacy. This entire proprietary technique allows Nexalin to provide a safe and comfortable treatment that is more powerful than any stimulation device in the market. Current pilot study protocols and randomized clinical trials have been designed and submitted to the FDA to provide feedback on final reports and data sets for the purpose of safety and efficacy evaluations in the future. Determinations of the safety and efficacy of our devices are solely within the authority of the FDA.

Currently, the waveform that comprises the basis of Gen-2 and new Gen-3 headset devices has been tested in research settings to develop safety data that has been submitted for review by the FDA for safety evaluation and eventual marketing in the United States and around the world. Determinations of the safety and efficacy of our devices in the United States are solely within the authority of the FDA.

We recognize that an additional barrier to treatment in today's mental health treatment landscape -- beyond the concerns about safety, efficacy and side-effects that have been associated with conventional mental health treatments such as ECT (shock therapy), drugs and psychotherapy -- is stigma. We have received industry reports and feedback that many patients that struggle with mood disorders have the stigma of embarrassment associated with psychiatrists and psychotherapy (e.g., counselling with a therapist). Additional stigmas and other issues are associated with the side effects of medication prescribed by psychiatrists. When we researched the current pharmaceuticals model, public information highlighted the many side effects associated with these medications. Frequently, patients would stop taking the medication because of the uncomfortable side effects. Additional public information mentions dependency and withdrawal issues associated with medication for psychiatric disorders.

To address the embarrassment stigma, we are developing a new virtual clinic that will allow the physician to diagnose a mental health issue in the privacy of a tele-psychiatry virtual platform. After diagnosis, the physician will prescribe the Nexalin Gen-3 headset to the patient for treatment. Next, the Gen-3 device will be shipped to the patient's home. After patient receives the device, they will pair the headset device with an app in the patient's smart phone. The app will communicate with the Nexalin cloud servers to authorize the device for treatment according to the protocol designed by the physician. The physician will monitor treatment compliance and other health related issues in a private physician dashboard that connects through the Nexalin app and cloud servers. We believe that to preserve product safety and integrity for home use, the headset device will require physician oversight that will include a prescription for use with a monthly authorization provided by the physician after a monthly virtual visit. All appointments will be in a virtual setting to provide privacy and convenience for the physician and patient. The Nexalin virtual clinic will be provided in a proprietary virtual platform currently in the design stage.

Our China Gen-2 15 milliamp device was recently approved in China by the NMPA for the treatment of insomnia and depression in China. This device and all other clinical devices will include a single use electrode for long term revenue streams. The USA Gen-2 device will have a fresh and modern appearance that meets the technology standards of the digital tech world of 2023. Early adopters of the Gen-1 device will be able to access additional firmware upgrades which are planned to enhance the previously purchased devices to the new symmetric 15-milliamp waveform. Our Gen-2 device will be equipped with RFID technology that exchanges electrode usage data with a reader in the main device. The purpose of RFID is to track and maintain control of the proprietary single use electrode. Our electrode chip will be programmed to exchange data with the device and allow activation for a single treatment with a new electrode only. This ensures a recurring revenue stream on the device and protects against any generic knockoffs designed to avoid treatment costs. This upgrade in technology also ensures the proprietary nature of the electrodes that support treatment outcomes are sustained.

Overall, we believe that our advanced waveform, technological upgrades and the development of a modern headset monitored with our IT management platform will position us with the opportunity to disrupt the traditional mental health treatment model. Our mission is to remove the stigma of expensive psychotherapy or pharmaceuticals with the attendant side effects and dependency issues and replace such stigma with clinically proven and cost-effective technology that is easily accessible in the privacy of the patient's home and monitored by licensed healthcare providers.

Since our inception, we have generated significant losses; we expect to continue to incur significant expenses and increasing operating losses for at least the next two years. Our net losses may fluctuate significantly from period to period, depending on the timing of our planned clinical trials and expenditures for other research and development activities. We expect our expenses will increase substantially over time as we:

- Continue the ongoing and planned preclinical and clinical development of our products;
- review and analyze the value of amending our previous 510(k) Application for anxiety and insomnia in accordance with the FDA and seek other regulatory approvals for any future products that successfully complete clinical trials;
- arrange for a sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize any product candidate for which we may obtain regulatory approval and intend to commercialize on our own;

- maintain, expand and protect our intellectual property portfolio;
- engage additional clinical, scientific, manufacturing and controls personnel;
- add additional operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts;
- seek to discover and develop additional products; and
- initiate preclinical studies and clinical trials for any additional products that we may pursue in the future.

Furthermore, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company.

## *Recent Developments*

### *Completion of Initial Public Offering*

The Company completed its initial public offering on September 16, 2022. The initial public offering consisted of 2,315,000 units consisting of 2,315,000 shares of its Common Stock and 2,315,000 accompanying warrants to purchase up to 2,315,000 shares of common stock. Each share of common stock was sold together with one warrant, each to purchase one share of common stock with an exercise price of \$4.15 per share at a combined offering price of \$4.15, for gross proceeds of \$9,607,250 before deducting underwriting discounts and offering expenses. In addition, Nexalin granted the underwriters a 45-day option to purchase up to an additional 347,250 shares of common stock and/or warrants to purchase up to 347,250 shares of common stock to cover over-allotments at the initial public offering price, less the underwriting discount. The underwriters exercised their option to purchase 347,250 warrants for net proceeds of \$3,473.

The registration statement on Form S-1 (File No. 333-261989) for our initial public offering was filed with the Securities and Exchange Commission ("SEC") and became effective on September 15, 2022. A final prospectus relating to the offering was filed with the SEC and is available on the SEC's website at <http://www.sec.gov>. The offering was being made only by means of a prospectus forming part of the effective registration statement.

The shares and warrants began trading on the Nasdaq Capital Market tier of the Nasdaq Stock Market ("Nasdaq") in September 2022, under the symbols "NXL" and "NXLW", respectively.

### *Impact of COVID-19 Pandemic*

We continue to monitor how the COVID-19 pandemic is affecting our employees, business and clinical trials. Such pandemic has delayed our clinical trials and our receipt of marketing approvals from the FDA. Such pandemic also might have reduced, and continue to reduce, participation in our clinical trials, due to both travel restrictions and a general unwillingness of subjects to travel. We cannot presently predict the scope and severity of any other potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage, including the suppliers, clinical trial sites, regulators and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted.

We continue to be indirectly impacted because of our current dependence upon our distributor relationship with Wider Come Limited ("Wider"). Wider acts as a distributor for the Company's devices in China and Asia. Because of significant restrictions imposed by the Chinese government during the Covid pandemic, Wider's ability to market and sell the Company's devices has been negatively impacted, resulting in decreased revenue to the Company. Patients and salespeople are restricted in their movements resulting in a significant slowdown in the medical and other sectors. Fortunately, our Chinese distributor continues our strategy of multiple clinical studies in the major institution in Beijing in an array of brain related diseases. Very significant efforts and funds expended by our Chinese distributor has led to regulatory approval in China in both depression and insomnia thus far which has allowed for sales of our devices in China this year. The extent of future impact will depend on future developments, including future activities by the Chinese government and other possible events which are highly uncertain and not in the Company's control, including new information which may emerge concerning the spread and severity of COVID-19, or any of its variants, and actions taken to address its impact, among others.

In addition, the spread of an infectious disease, including COVID-19, may also result in the inability of our suppliers to deliver components or raw materials on a timely basis. Such events may result in a period of business and manufacturing disruption, and in reduced operations, any of which could materially affect our business, financial condition and results of operations. The extent to which the coronavirus impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain the coronavirus or treat its impact, among other things.

### *Potential Joint Venture; China Related Activities*

In September 2018, we entered into an agreement with Wider Come Limited, a company formed under the laws of the People's Republic of China ("Wider"), pursuant to which we and Wider have agreed to investigate the formation of a joint venture entity to be domiciled in Hong Kong (the "potential Joint Venture") to conduct additional clinical research and implement a business distribution plan for our devices in China, Macau, Hong Kong, and Taiwan. We do not have any existing operations in China and will not in the future. We do have current distribution in China through Wider, our potential Joint Venture partner. As of the date of this Annual Report on Form 10-K, (i) our operations are carried on outside of China; and (ii) the potential Joint Venture does not maintain any variable interest entity structure or operate any data center in China. However, because of the intended formation of the potential Joint Venture, we may become subject to laws of The People's Republic of China (PRC or China) relating to, among other topics, data security and restrictions over foreign investments. Further, as a result of the complexity and vagaries of the legal system in the PRC and recent statements and regulatory actions by the PRC government relating to data security, our ability to operate the potential Joint Venture may be adversely affected or subject to change and adversely impact our ability to offer or continue to offer securities to investors, with the result that our securities may significantly decline or be worthless. There can be no assurance that regulators in China will not take a contrary view or will not subsequently require us to undergo the approval procedures and subject us to penalties for non-compliance.

In March 2022, we entered into a second supplement to the Joint Venture agreement with Wider whereby the parties confirmed that the potential Joint Venture had not yet been established and is subject to further review and analysis of regulatory issues in China and the United States. Pursuant to the second supplement, the parties agreed to use their commercial efforts to complete documentation by September 30, 2022. In light of general economic conditions in China and the United States, the continued impact of regulatory issues within China and the United States and trade and political issues between the two countries, the parties determined to further extend the time frame to complete establishment of the joint venture to September 30, 2023 and entered into a Supplement 3 to the potential Joint Venture Agreement to memorialize such extension. The parties intend to continue to work together to complete the establishment prior to such extended time. Further, the parties agreed that all references within the Joint Venture agreements to funding and formation were amended from December 21, 2018 to be September 30, 2023. We anticipate that the Joint Venture will be formed by the third quarter of 2023. However,



that will be dependent on the situation at that time.

When and if the Joint Venture is formed and Wider completes sales of our devices in China on behalf of the potential Joint Venture, we believe that there are no regulatory or other restrictions that would restrict either (i) the transfer from China of any proceeds resulting from such sales by Wider to the potential Joint Venture in Hong Kong, other than standard compliance with China's State Administration of Foreign Exchange ("SAFE") policies and approval process, or (ii) our receipt of our share of such proceeds from Hong Kong to us in the United States, which is not subject to SAFE's policies and approval process. The Company does not currently believe any of the Company's scientific data resulting from activities in China by the potential Joint Venture would fall within the Measures for the Management of Scientific Data promulgated by the General Office of the PRC State Council. In the event any existing or new laws or regulations or detailed implementations and interpretations are modified or promulgated, we and the potential Joint Venture will take all actions to remain in compliance with any such laws or regulations or detailed implementations and interpretations thereof. Neither we nor our potential Joint Venture Partner can at this point speak to any future changes in rules, regulations or the commercial and potentials situation that lies ahead which could affect the formation of the Joint Venture.

In September of 2021, the China National Medical Products Administration (NMPA), the equivalent of the United States FDA, approved the Gen-2 device for marketing and sale in China for the treatment of insomnia and depression. These treatment indications and clearances from the NMPA have allowed Wider to market and sell the Gen-2 device in China for the treatment of insomnia and depression.

## Results of Operations

### Comparison of the Years ended December 31, 2022 and 2021

Our financial results for the years ended December 31, 2022 and 2021 are summarized as follows:

	Years Ended		Change \$	Change <sup>(1)</sup> %
	December 31, 2022	December 31, 2021		
Revenues, net	\$ 1,321,357	\$ 144,065	\$ 1,177,292	817%
Cost of Revenues	363,212	21,442	341,770	1,594%
Gross profit	958,145	122,623	835,522	681%
Operating expenses:				
Professional fees	605,329	697,063	(91,734)	(13)%
Salaries and benefits	694,108	228,738	465,370	203%
Selling, general and administrative	1,491,739	5,215,423	(3,723,684)	(71)%
Total operating expenses	2,791,176	6,141,224	(3,350,048)	(55)%
Loss from operations	(1,883,031)	(6,018,601)	4,185,570	(70)%
Other income (expense), net:				
Interest expense, net	(59,382)	(82,319)	22,937	28%
Other income	171,681	-	171,681	100%
PPP loan forgiveness	22,916	22,916	-	-
Total other income (expense), net	135,215	(59,403)	194,618	328%
Net loss	(1,697,816)	(6,078,004)	4,380,188	72%
Other comprehensive income:				
Unrealized gain on short-term investments	36,313	-	36,313	100%
Comprehensive loss	\$ (1,661,503)	\$ (6,078,004)	\$ 4,416,501	73%

(1) Percentages may not foot due to rounding.

### Revenues

For the years ended December 31, 2022 and 2021, we generated \$1,321,357 and \$144,065, respectively, of revenue primarily from the sale of devices, supplies and from the reimbursement of costs. In addition, we generated income from licensing and treatment fee agreements with our customers by charging a monthly licensing fee for the duration of the agreement. We also generated revenue from treatment fee agreements by collecting fees based on the number of treatments per month the customer performs. In addition, we derive revenue from equipment by selling electrodes and patient cables to customers for use with our device. The increase in revenue for 2022 compared to 2021 was primarily due to the sale of 221 devices in 2022. There were no sales of devices in 2021.

### Cost of Revenues and Gross Profit

For the years ended December 31, 2022 and 2021, cost of revenues were \$363,212 and \$21,442, respectively, yielding a gross profit of \$958,145 and \$122,623, respectively, or 73% and 85%, respectively. Such decrease in gross margin was due to the change in our sources of revenue. In 2021 our revenue was from licensing fees and the sales of electrodes and patient cables. The licensing fees have no related costs. Our cost of revenue in 2021 included shipping supplies and the cost of the electrodes and patient cables. In 2022 our revenue was primarily from sales of equipment. The equipment has higher related costs of revenue and related shipping costs.

### Operating Expenses

Total operating expenses for the years ended December 31, 2022 and 2021 were \$2,791,176 and \$6,141,224, respectively. The decrease was primarily due to the decrease of approximately \$4,200,000 in stock-based compensation for the issuance of our common stock to various employees and consultants for services, and a decrease in professional fees for legal and accounting of approximately \$100,000 offset by an increase in salaries and related expenses of approximately \$465,000, an increase in research and development costs of approximately \$372,000, an increase in consulting costs of approximately \$80,000, and an increase in insurance of approximately \$88,000. The decrease in legal and accounting fees are primarily due to the treatment of costs relating to our initial public offering as a direct cost of the offering. The increase in salary is primarily due to the hiring of our CFO, our Senior Vice President of Quality, Clinical and Regulatory, and other staff. The increases in research and development and consulting costs are attributable to the

development of our Gen-2 and Gen-3 devices. The increase in insurance is a result of being a public company.

#### Other Income (Expense), net

Other income (expense), net, as of December 31, 2022 and 2021 were \$135,215 and (\$59,403), respectively, consisting of interest expense net of the PPP loan forgiveness, settlement income as a result of interest forgiveness, and interest and dividend income.

#### *Liquidity and Capital Resources*

##### **Working Capital**

	As of	
	December 31, 2022	December 31, 2021
Current Assets	\$ 7,425,462	\$ 752,659
Current Liabilities	1,948,986	2,363,634
Working Capital	\$ 5,476,476	\$ (1,610,975)

Current assets increased for the year ended December 31, 2022 primarily as a result of the proceeds of the Initial Public Offering. Cash and cash equivalents decreased approximately \$500,000, Short-term investments increased approximately \$6,800,000, accounts receivable decreased approximately \$10,000, inventory increased approximately \$125,000 and prepaid and other current assets increased approximately \$230,000.

Current liabilities decreased for year ended December 31, 2022 primarily as a result of the reduction of accounts payable, settlement of accrued interest and a decrease in deferred revenue. Accounts payable decreased approximately \$185,000, accrued expenses decreased approximately \$72,000, lease liability – current portion increased approximately \$10,000, and deferred revenue decreased approximately \$130,000.

##### **Cash Flows**

The following table summarizes our consolidated cash flows for the twelve months ended December 31, 2022 and 2021:

	December 31, 2022	December 31, 2021
Net cash used in operating activities	\$ 2,215,699	\$ 1,076,791
Net cash used in investing activities	\$ 6,794,879	\$ -
Net cash provided by financing activities	\$ 8,511,543	\$ 1,660,133

#### Net Cash Used In Operating Activities

Net cash used in operating activities was \$2,215,699 for the year ended December 31, 2022, as compared to \$1,076,791 for the respective period in 2021, primarily due to the net loss of \$1,697,816 and \$6,078,004, respectively, as well as increases in accounts payable, deferred revenue, prepaid assets and inventory. These amounts were also offset by \$270,670 and \$4,478,035 of stock compensation during the periods, respectively.

#### Net Cash Used In Investing Activities

Net cash used in investing activities during the year ended December 31, 2022 and 2021 was \$6,794,879 and zero, respectively, which was due to the 2022 purchase of short-term investments.

#### Net Cash Provided by Financing Activities

Net cash provided by financing activities during the year ended December 31, 2022 and 2021 was \$8,511,543 and \$1,660,133, respectively, which was primarily due to the sale of common stock at IPO, for cash in 2022 and 2021.

#### **Uses and Availability of Additional Funds**

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical research and development services, manufacturing development costs, legal and other regulatory expenses, and general administrative costs. Although we have produced Gen-2, which is selling in China where it is approved for certain utilizations by medical practitioners, the successful development of our future products is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the clinical development of Gen-3 and obtain regulatory approvals. We are also unable to predict when, if ever, net cash inflows from revenues will enable us to be cash flow positive. This is due to the numerous risks and uncertainties associated with developing products, including, among others, the uncertainty of:

- successful enrollment in, and completion of clinical trials;
- performing preclinical studies and clinical trials in compliance with the FDA or any comparable regulatory authority requirements;
- the ability of collaborators to manufacture sufficient quantity of product for development, clinical trials and/ or potential commercialization;
- obtaining and maintaining patent, trademark and trade secret protection for our products;
- making arrangements with third parties for manufacturing;
- scaling the commercial sales of products, if and when approved, whether alone or in collaboration with others;
- acceptance of existing therapies, and future therapies, if and when approved, by healthcare providers, physicians, clinicians, patients and third-party payors;
- competing effectively with other therapies;

- obtaining and maintaining healthcare coverage and adequate reimbursement;
- protecting our rights in our intellectual property portfolio; and
- maintaining a continued acceptable safety profile of our products following approval.

#### *Liquidity and Capital Resources*

At December 31, 2022, the Company had a significant accumulated deficit of \$72.4 million. For the year ended December 31, 2022, the Company had a loss from operations of \$1.8 million and negative cash flows from operations of \$2.2 million. The Company's operating activities consume the majority of its cash resources. The Company will continue to service existing customers in the United States. The Company sold devices in China to its acting distributor. The Company anticipates that it will continue to incur operating losses as it executes its development plans through 2023, as well as other potential strategic and business development initiatives. In addition, the Company has had and expects to have negative cash flows from operations, at least into the near future. The Company previously funded these losses primarily through the sale of equity and issuance of convertible notes. The accompanying audited consolidated financial statements do not include any adjustments that might be necessary should the Company be unable to continue as a going concern. As of the year ended December 31, 2022, the Company had cash and cash equivalents on hand of \$162,743 and short-term investments of \$6,831,192.

At the closing on September 16, 2022, the Company sold 2,315,000 Units and 347,250 of Warrants in an Initial Public Offering (the "Initial Public Offering") at a price of \$4.15 per Unit and \$0.01 per Warrant for a total of \$9,610,723. The Company incurred offering costs of \$1,067,078, consisting of \$878,858 of underwriting fees and expenses and \$188,220 of costs related to the Initial Public Offering.

Although no assurances can be given as to the Company's ability to deliver on its revenue plans or that unforeseen expenses may arise, management has evaluated the significance of the conditions and has concluded that because of the completion of our initial public offering in September 2022, the Company has sufficient cash and investments on hand to satisfy its anticipated cash requirements for the next twelve months from the issuance date of these financial statements.

#### *Critical Accounting Policies and Significant Judgments and Estimates*

Our audited consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our audited consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our audited consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 3 to our consolidated financial statements appearing elsewhere in this Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

#### **Revenue Recognition**

The Company recognizes revenue when its performance obligations with its customers have been satisfied. At contract inception, the Company determines if the contract is within the scope of ASC Topic 606 and then evaluates the contract using the following five steps: (1) identify the contract with the customer; (2) identify the performance obligations; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations; and (5) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only recognizes revenue to the extent that it is probable that a significant revenue reversal will not occur in a future period.

The Company has existing licensing and treatment fee agreements with its customers for the use of the Nexalin Device in their practices. These agreements generally have terms of one year with automatic renewal if certain requirements are met and amounts due per these agreements are billed monthly. The Company also sells products related to the provision of services. The Company sells its Devices in China to its acting distributor and sells products relating to the use of the Devices. The Company has a Royalty Agreement whereby the manufacturer of the Company's electrodes will pay a royalty to the Company for a three year period beginning January 1, 2022. The amount of the Royalty is equal to 20% of the amount that the manufacturer invoices to the acting distributor for the sale of the electrodes.

#### Revenue Streams

The Company derives revenues from its license agreements by charging a monthly licensing fee for the duration of the agreement. The Company derives revenues from equipment by selling additional individual electrodes and patient cables to customers for use with the Nexalin Device. The Company receives revenue from the sale in China of its Devices to its acting distributor and from the sale of products relating to the use of those Devices. The Company derives revenue as a royalty fee from the China-based manufacturer for electrodes ordered in connection with the Company's China sales.

#### Performance Obligations

Management identified that subsequent licensing revenue has one performance obligation. That performance obligation is satisfied as long as the licensing contract remains valid and is not terminated. The licensing revenue is invoiced monthly and is recognized at a point in time in which the invoice is sent to the customer.

Management identified that our equipment revenue has one performance obligation. That performance obligation is satisfied when the electrodes and devices are shipped to the customer. We do not offer a warranty on the electrodes or devices.

Management identified that treatment fee revenue has one performance obligation. The performance obligation is satisfied upon the completion of individual treatments on patients by customers.

Management identified that our royalty fee has one performance obligation. The performance obligation is satisfied as long as the royalty agreement remains valid and is not terminated. The royalty revenue is invoiced when the manufacturer advises the Company that the invoice has been sent to the customer.

#### Practical Expedients

As part of ASC 606, the Company has adopted several practical expedients including:

- **Significant Financing Component** — we do not adjust the promised amount of consideration for the effects of a significant financing component since we expect, at contract inception, that the period between when we transfer a promised goods or services to the customer and when the customer pays for that service will be one year or less.
- **Unsatisfied Performance Obligations** —for all performance obligations related to contracts with a duration of less than one year, we have elected to apply the optional exemption provided in ASC Topic 606 and therefore, are not required to disclose the aggregate amount of the transaction price allocated to performance obligations that are unsatisfied or partially unsatisfied at the end of the reporting period.
- **Shipping and Handling Activities** — we elected to account for shipping and handling activities as a fulfillment cost rather than as a separate performance obligation.
- **Right to invoice** — we have the right to consideration from a customer in an amount that corresponds directly with the value to the customer of our performance completed to date we may recognize revenue in the amount to which the entity has a right to invoice.

#### *Recent Accounting Pronouncements*

In November 2021, the FASB issued ASU 2021-10, Government Assistance (Topic 832). ASU 2021-10 and its amendments will be effective for the Company for interim and annual periods in fiscal years beginning after December 15, 2021. The Company believes the disclosure requirements related to governmental assistance have been appropriately made, specifically pertaining to PPP Loans that were forgiven by the government in 2021. The total impact of the forgiveness on the consolidated financial statements was immaterial.

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In February 2020, the FASB issued ASU 2020-02, Financial Instruments-Credit Losses (Topic 326) and Leases (Topic 842) - Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 119 and Update to SEC Section on Effective Date Related to Accounting Standards Update No. 2016-02, Leases (Topic 842), which amends the effective date of the original pronouncement for smaller reporting companies. ASU 2016-13 and its amendments will be effective for the Company for interim and annual periods in fiscal years beginning after December 15, 2022. The Company believes the adoption will modify the way the Company analyzes financial instruments, but it does not anticipate a material impact on results of operations. The Company is in the process of determining the effects adoption will have on its audited consolidated financial statements.

All other newly issued but not yet effective accounting pronouncements have been deemed to be not applicable or immaterial to the Company.

#### *Factors That May Affect Future Results and Financial Condition*

The information contained under the caption "Risk Factors" beginning on page 15 of this Form 10-K provides examples of risks, uncertainties and events that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. Readers should be aware that the occurrence of any of the events described in these risk factors could have a material adverse effect on our business, results of operations and financial condition. We undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events, or otherwise.

#### *Quantitative and Qualitative Disclosures about Market Risk*

Not Applicable. As a smaller reporting company, we are not required to provide the information required by this Item.

#### *Use of proceeds from our Initial Public Offering*

The Company completed its initial public offering on September 16, 2022. A registration statement on Form S-1 (File No. 333-261989) for our initial public offering was filed with the Securities and Exchange Commission ("SEC") and became effective on September 15, 2022. The initial public offering consisted of 2,315,000 units consisting of 2,315,000 shares of its Common Stock and 2,315,000 accompanying warrants to purchase up to 2,315,000 shares of common stock. Each share of common stock was sold together with one warrant, each to purchase one share of common stock with an exercise price of \$4.15 per share at a combined offering price of \$4.15, for gross proceeds of \$9,607,250, before deducting underwriting discounts and offering expenses. In addition, we granted the underwriters a 45-day option to purchase up to an additional 347,250 shares of common stock and/or warrants to purchase up to 347,250 shares of common stock to cover over-allotments at the initial public offering price, less the underwriting discount. The underwriter partially exercised the over-allotment for 347,200 warrants for net proceeds of \$3,473. We received net proceeds of \$8,543,645 (after underwriting and offering expenses of \$1,067,078) from this initial public offering. As of December 31, 2022, we utilized the net proceeds to support our daily operations, approximately \$406,000 to fund research and development work, approximately \$63,000 for regulatory and certification costs, \$237,419 to pay past due service fees to U.S. Asian Consulting Group, LLC and approximately \$285,000 for legal, accounting and administrative expenses.

#### **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

The Company has not engaged in trading practices in securities or other financial instruments and therefore does not have any material exposure to interest rate risk, foreign currency exchange rate risk, commodity price risk or other similar risks, which might otherwise result from such practices. The Company has no foreign operations and therefore is not materially subject to fluctuations in foreign exchange rates, commodity prices or other market rates or prices from market sensitive instruments.

#### **ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTAL DATA**

See attached Consolidated Financial Statements beginning on page F-1 attached to this Report on Form 10-K.

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#### **ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

As previously reported on Form 8-K filed with the Securities and Exchange Commission on October 3, 2022, based on information provided by the Company's independent registered public accounting firm, Friedman LLP, effective September 1, 2022 Friedman LLP combined with Marcum LLP and continued to operate as an independent registered public accounting firm. On September 30, 2022, the Audit Committee of the Board of Directors of the Company approved the dismissal of Friedman LLP and the engagement of Marcum LLP to serve as the independent registered public accounting firm of the Company. The services previously provided by Friedman LLP are now be provided by Marcum LLP. There are no disagreements with accountants on accounting and financial disclosure.

#### **ITEM 9A. CONTROLS AND PROCEDURES**

##### *Evaluation of Disclosure Controls and Procedures*

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-

15(f) and 15d-15(f). Internal control over financial reporting is a process designed by, or under the supervision of, our principal executive officer and principal financial officer, or persons performing similar functions, and effected by our board of directors to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements. Our management evaluated, with the participation of our chief executive officer and chief financial officer (our "Certifying Officers"), the effectiveness of our disclosure controls and procedures as of December 31, 2022, pursuant to Rule 13a-15(b) under the Exchange Act. Based upon that evaluation, our Certifying Officers concluded that, as of the evaluation date, our disclosure controls and procedures were not effective due to the following material weaknesses:

- Lack of sufficient resources necessary to provide adequate segregation of duties related to the preparation and review of financial information used in financial reporting and review of controls over the financial reporting process, including documentation of review/approval of journal entries and reconciliations; and
- Insufficient IT controls which are effectively designed and implemented, specifically related to user/superuser access to the Company's financial reporting system

The deficiencies described above if not remedied, could result in a misstatement of one or more account balances or disclosures in our annual or interim consolidated financial statements that would not be prevented or detected, and, accordingly, we determined that these control deficiencies constitute a material weakness.

To address our material weakness, we intend to engage an outside firm to advise on our financial reporting processes, and intend to implement new financial accounting controls and processes. We intend to continue to take steps to remediate the material weakness described above through implementing enhancements and controls within our accounting systems, subject to budget limitations. We will not be able to remediate these control deficiencies until these steps have been completed and have been operating effectively for a sufficient period of time and Management has concluded, through testing, that the controls are operating effectively. The redesign and implementation of improvements to our accounting and proprietary systems and controls may be costly and time consuming and the cost to remediate may impair our results of operations in the future.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

#### *Management's Report on Internal Controls over Financial Reporting*

This report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by the rules of the Commission for newly public companies.

We are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K under the Securities Act. For as long as we continue to be a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not smaller reporting companies. Additionally, this Report does not contain an attestation report of our registered public accounting firm regarding internal control over financial reporting since the Company, as a non-accelerated filer and "emerging growth company," is not required to provide such report.

#### *Changes in Internal Control over Financial Reporting*

There were no changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### **ITEM 9B. OTHER INFORMATION**

None.

#### **ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTION**

Not Applicable

### **PART III**

#### **ITEM 10. DIRECTORS, EXECUTIVES AND CORPORATE GOVERNANCE**

##### *Directors and Executive Officers*

The following table sets forth the name, age as of December 31, 2022, and position of the individuals who currently serve as our directors and executive officers. The following also includes certain information regarding the individual experience, qualifications, attributes and skills of our directors and executive officers as well as brief statements of those aspects of our directors' backgrounds that led us to conclude that they are qualified to serve as directors.

<b>Name</b>	<b>Age</b>	<b>Position</b>
<i>Executive Officers:</i>		
Mark White	62	President, Chief Executive Officer, Director
David Owens, M.D.	61	Chief Medical Officer, Director
Marilyn Elson	69	Chief Financial Officer
Michael Nketiah	47	Senior Vice President of Quality, Clinical and Regulatory
<i>Non-Employee Directors:</i>		
Rick Morad	64	Director
Alan Kazden	62	Director
Ben Hu, M.D.	65	Director

**Mark White, President and Chief Executive Officer, Board of Directors**

Mr. Mark White has been with Nexalin since 2012, first as an independent consultant from 2012 to 2018, and then as President and Chief Executive Officer from 2018 to present. Mr. White is a versatile health technology executive with over twenty-five years in leadership roles spanning medical device development, clinical operations and business development. Prior to joining Nexalin, he owned and operated his own clinics and addiction centers, where he has saw first-hand the positive results the technology achieves. Early in his career, Mr. White spent several years building companies and recruiting successful management teams to accelerate growth across several industries. Mr. White attended the University of Houston.

**David Owens M.D., Chief Medical Officer, Board of Directors**

Dr. David Owens has been with Nexalin since 2017 when he was named Chief Medical Officer of the Company. Dr. Owens has been involved in numerous medical and software ventures over the past decade. Prior to joining Nexalin, he served with Empiric Systems, LLC, a software company specializing in radiology information systems and PACS viewing systems. He received a degree in chemistry and physics from Furman University and later a M.D from the Medical University of South Carolina in Charleston. He completed his residency and fellowship at Emory University Hospital in Neuroradiology and Interventional Neuroradiology.

**Marilyn Elson, Chief Financial Officer**

Ms. Marilyn Elson joined Nexalin as Chief Financial Officer in January 2022 and has been a Certified Public Accountant for approximately 35 years providing services for a range of clients including real estate partnerships, corporations and high net worth individuals. Ms. Elson is a shareholder of the Company. She is a member of U.S. Asian Consulting Group, LLC, which renders advice and consulting services, including services to the Company and which receives consulting fees from the Company.

Ms. Elson provides services from time to time to a boutique accounting firm whose predecessor Ms. Elson cofounded and of which she was a member. Ms. Elson terminated her ownership status with that firm in order to serve as Comptroller for a medical technology company guiding the company through a public offering and listing on a stock exchange. Ms. Elson received a BA in Accounting from Queens College and a MS in Taxation from Pace University.

**Michael Nketiah, Senior Vice President of Quality, Clinical and Regulatory**

Michael Nketiah joined the Company in December, 2022 as its Senior Vice President of Quality, Clinical and Regulatory. He is an expert in regulatory affairs, clinical and quality assurance specializing in US FDA and international regulatory approvals with over 23 years working directly with the FDA in the medical device and life sciences industries. His experience includes developing quality systems, authoring various US FDA regulatory submissions, and assisting with clinical operations. From November 2021 to October 2022 he was Vice President of Quality and Regulatory Affairs at Intervenn Bioscience. From April 2019 to November 2021 Mr. Nketiah was Vice President of Quality and Regulatory Affairs at Tivie Health Systems, Inc. He also served as vice President Quality, Regulatory Affairs and Operation at Siris Medical Inc. from November 2015 to April 2019 and held similar positions at various companies such as ClearPath Surgical, Previvo Genetics, Inc. and other companies over the prior ten years. Michael holds two (2) Bachelor of Science degrees in Chemistry and Mechanical Engineering, and an MBA degree.

**John Patrick Claude**

Mr. John Claude, in conjunction with Dr. Yakov Katsnelson, designed and developed the original tACS waveform that is marketed as Nexalin Technology. Mr. Claude now leads all engineering, research and development at Nexalin Technology. Additionally, Mr. Claude has an extensive background in regulatory, compliance and quality management. Mr. Claude graduated from the University of Notre Dame with a BS in Physiology. He subsequently received an ME in Biomedical Engineering from the University of Virginia. Mr. Claude has designed and built advanced technologies for NASA, NIH, Stanford Medical Center and the Palo Alto Veterans Administration.

*Non-Employee Directors*

**Rick Morad, Chairman of the Board**

Mr. Rick Morad is a founding investor and shareholder in Nexalin. He has served on our board of directors since 2018. Mr. Morad has been a successful business operator since 1987. Mr. Morad is also a licensed attorney. Mr. Morad received a B.S./B.A. in business administration, with a major in Finance and a minor in Accounting, from John Carroll University. He also received a J.D., and graduated with high honors, from John Marshall Law School.

**Alan Kazden**

Mr. Alan Kazden was an original investor in Nexalin and has served as a Director since 2019. Mr. Kazden has over 30 years of diverse experience consulting with emerging growth companies in strategic business planning, partnering, raising capital, and acting as a virtual CFO. Prior to joining Nexalin, Mr. Kazden worked in various industries such as technology, manufacturing & distribution, real estate, health care, entertainment, and emerging growth companies. He also previously served as a consultant to the Mayor's Office and Los Angeles City Council on local tax issues.

**Ben V. Hu MD.**

Dr. Ben V. Hu is a founding investor and shareholder in Nexalin. Dr. Hu is currently in private practice in Ohio, focusing on Ophthalmology. Since 2018, he has advised the Nexalin executive team on market development strategies and clinical trial structures to support marketing and distribution at a global level. Dr. Hu is also an advisor and member of the Board of Directors to Med-logics Inc. a company developing a surgical technology for cataract surgery utilizing a new patented technology. Dr Hu was awarded his Doctor of Medicine in 1983 from Case Western University and his Chemical Engineering degree from MIT School of Chemical Engineering.

*Medical Board Advisors*

Our Medical Board advises our management team in planning, development and execution of scientific, clinical and research and development initiatives and strategies. Our Medical Board consists of experts across a range of key disciplines relevant to our initiatives.

Our current Medical Board advisors are:

**Abe Scheer, MD.**

Dr. Abraham Scheer specializes in both neurology and psychiatry. Dr. Scheer has over forty years of experience in the field of neurosciences. Dr. Scheer has lectured extensively throughout the United States on neuromodulation devices. Dr. Scheer was part of the Speakers' Bureau for both Medtronic's and Cyberonic's Neuromodulating Divisions. His clinical expertise includes Adult and Child Neurology, Brain Injury Medicine and Adult and Child Psychiatry. Dr. Scheer has trained and worked at the finest medical institutions in the United States, which include Columbia University College of Physicians and Surgeons, Cornell Medical College, George Washington University, Georgetown University, University of Connecticut and the University of Pittsburgh. Dr. Scheer served as Director of Neurology and Stroke Services for Beebe Healthcare in Delaware. He is currently a neurohospitalist/neurointensivist for Bay Health in Delaware. Dr. Scheer is the cousin of our Chief Financial Officer, Marilyn Elson.

Dr. Scheer and the Company entered into consulting agreements whereby Dr. Scheer agreed to provide consulting services to the Company during the years ended December, 2021 and December 2022. For his services he was compensated with 10,000 shares of common stock of the Company for each year of service. Dr. Scheer's current agreement with the Company has expired. The Company and Dr. Scheer are discussing terms of a new consulting arrangement.

#### **Irene Cergnul, M.D.**

Dr. Irene Cergnul completed her postgraduate training at Bronx Lebanon Hospital Center in New York and after her final year as Chief Resident was recruited as Assistant Professor/Faculty in the Department of Family Medicine. She worked as the Medical Director in the in-patient service and taught residents in training for the next four years. She was a Research Coordinator involving multiple studies on HIV, depression, as well as neuropathy, and is a co-author on several publications.

Dr. Cergnul has been involved in the field of addiction medicine, HIV care and mental health for the last seventeen years. She is committed to developing and integrating current and new modalities in the treatment of addictive disorders and has dedicated her working career to treating the underserved population in NY and NJ. Her private practice focuses on novel modalities used in treating addiction and dual diagnosis patients and has successfully incorporated Nexalin as an integral part of her treatment armamentarium.

#### **Nancy White, Ph.D.**

Dr. Nancy White is the Clinical Director of Unique Mind Care in Houston, Texas. She is recognized as an industry leader in the development of a brain-based approach to support neurobehavioral wellness. Dr. White has specialized in the diagnosis and treatment of functional brain disorders for more than twenty years. She is a Fellow, past President and Board member of the International Society for Neurofeedback and Research (ISNR), a Certified EEG Fellow of the Biofeedback Certification International Alliance (BCN) and a QEEG Diplomate and member of the Quantitative EEG Certification Board. Dr. White is a licensed Clinical Psychologist in the State of Texas as well as an Advanced Addictions Counselor.

Dr. White is a pioneer in the practical application of neuroscientific research to clinical practice, including the extension of advanced brain-based therapies to all psychiatric mood disorders including Post-Traumatic Stress, Autism and Addictions. She is a frequent presenter of her work at conferences, including the American Academy of Anti-Aging Medicine, the International Society for Neurofeedback and Research, the Association for Applied Psychophysiology and Biofeedback, Future Health and the National Academy of Neuropsychology. She also serves as a consulting editor of the Journal of Neurotherapy (Taylor and Francis).

Dr. White has dedicated seven years to the development of the clinical application of the Nexalin therapy. Her research and clinical data on the use of Nexalin therapy has been presented at international conferences. Dr. White is the mother of our Chief Executive Officer, Mark White.

#### *Non-Medical Board of Advisors*

Nexalin has also established a non-medical Board of Advisors. The members of the Board of Advisors serve at the request of the Board and advise and make recommendations with respect to the strategic direction of the company and similar matters. The members of the Board of Advisors do not have, or shall be deemed to have, a fiduciary relationship in respect of the company. The members of the Board of Advisors are set forth below. We have entered into agreements with each member of the Board of Advisors, which set forth the terms and conditions relating to the individual's service on the Board of Advisors. The agreements provide for an initial one-year term, which can be extended for an additional year. The agreements commenced December 24, 2021 and include confidentiality and protection of Company's intellectual property, and indemnification protection. Under the agreements, each advisor is entitled to receive \$80,000 worth of our Common Stock. The value of the shares issuable is \$5.00 per share, which was the price of our Common Stock based upon transactions with unaffiliated third parties at such time. All the members of our Board of Advisors have waived compensation for fiscal 2022.

#### **Tucker Anderson**

Tucker Andersen spent twenty-seven years with the private investment partnership Cumberland Associates, including fifteen years as a co-managing partner of the firm. Subsequent to his retirement from that position, he founded Above All Advisors, a consulting and investment firm. He is on several advisory and private company boards, including, Questech Corporation, Value Insight Partners, and Artificial Cell Technologies. He received his B.A. in Quantitative Studies from Wesleyan University in 1963. Tucker is the recipient of both the Wesleyan Distinguished Alumnus Award and the Exeter Founder's Day Award. He is both a Chartered Financial Analyst and an Associate Member of the Society of Actuaries.

#### **Leonard Osser**

Leonard Osser has been a Director of Milestone Scientific, Inc. since he founded that company in 1989. He served as Chief Executive Officer of Milestone Scientific from the time of its founding until 2021, other than twice during the last 20 years when he intended to retire from that position. He served as Chairman of Milestone Scientific from 1991 until September 2009 at which time he resigned as Chairman of Milestone Scientific, but remained a director. Mr. Osser serves as Managing Member of U.S. Asian Consulting Group LLC, which provides various consulting services to the Company. Mr. Osser is a shareholder of the Company. He is a member of our non-medical Board of Advisors and serves as Director of China operations. Mr. Osser is the spouse of Marilyn Elson, our Chief Financial Officer.

#### **Gian Domenico Trombetta**

Gian Domenico Trombetta has been the President and CEO of Innovest S.p.A. an Italian corporation specializing in private equity and distressed assets since 1992. He was previously with Booz Allen & Hamilton Inc. focusing on strategy and acquisition services. Mr. Trombetta received B.A. from Luiss University in Rome in 1984. Mr. Trombetta is also an independent director of Milestone Scientific Inc.

#### *Family Relationships*

Ms. Marilyn Elson, our Chief Financial Officer, is the spouse of Leonard Osser, a member of our non-medical Board of Advisors and director of China Operations. Ms. Elson is the cousin of Abraham Scheer, one of the members of our Medical Board of Advisors. Dr. Nancy White, a member of our Medical Board of Advisors is the mother of Mr. Mark White, our Chief Executive Officer. Other than as stated in the preceding two sentences, there are no family relationships between any of our directors or executive officers.

## *Board Composition*

Our board of directors currently consists of five members. There are no contractual obligations regarding the election of our directors. Our nominating and corporate governance committee and our board of directors may therefore consider a broad range of factors relating to the qualifications and background of nominees. Our nominating and corporate governance committee's and our board of directors' priority in selecting board members is identification of persons who will further the interests of our stockholders through their established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business, understanding of the competitive landscape, professional and personal experiences and expertise relevant to our growth strategy. Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal. Our amended and restated certificate of incorporation and amended and restated bylaws provide that our directors may be removed only for cause by the affirmative vote of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast in an annual election of directors, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

Under our agreements with U.S. Asian Consulting Group LLC, U.S. Asian was granted a right to appoint one director to our Board of Directors. To date, U.S. Asian has not exercised this right.

## *Director Independence*

Our board of directors has undertaken a review of its composition, the composition of its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that all of our directors (Rick Morad, Alan Kazden and Ben Hu M.D.) other than Mark White and Dr. Owens have no relationships that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the applicable rules and regulations of the SEC and Nasdaq. In making this determination, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining his or her independence, including the beneficial ownership of our share capital held by each non-employee director.

## *Committees of the Board of Directors*

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which will have the composition and responsibilities described below. From time to time, the board may establish other committees to facilitate the oversight of our business. The charters for each of our committees is available on our website (<https://nexalin.com/>).

### **Audit Committee**

Our audit committee is composed of our three independent directors, Messrs. Alan Kazden, Rick Morad and Ben Hu M.D. Our board of directors has determined that each of these persons are independent within the meaning of applicable Nasdaq listing requirements and the independence requirements contemplated by Rule 10A-3 under the Securities Exchange Act of 1934, as amended. Alan Kazden is the chairman of the audit committee and our board of directors has determined that he is an "audit committee financial expert" as defined by SEC rules and regulations. Our board of directors has determined that the composition of our audit committee meets the criteria for independence under, and the functioning of our audit committee complies with, the applicable requirements of the Sarbanes-Oxley Act, applicable Nasdaq listing requirements and SEC rules and regulations. We intend to continue to evaluate the requirements applicable to us and we intend to comply with the future requirements to the extent that they become applicable to our audit committee. The principal duties and responsibilities of our audit committee include:

- appointing and retaining an independent registered public accounting firm to serve as independent auditor to audit our financial statements, overseeing the independent auditor's work and determining the independent auditor's compensation;
- approving in advance all audit services and non-audit services to be provided to us by our independent auditor;

- establishing procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls, auditing or compliance matters, as well as for the confidential, anonymous submission by our employees of concerns regarding questionable accounting or auditing matters;
- reviewing and discussing with management and our independent auditor the results of the annual audit and the independent auditor's review of our quarterly financial statements;
- conferring with management and our independent auditor about the scope, adequacy and effectiveness of our internal accounting controls, the objectivity of our financial reporting and our accounting policies and practices; and
- reviewing and approving any related party transaction required to be disclosed pursuant to Item 404 of Regulation S-K promulgated by the SEC prior to us entering into such transactions.

### **Compensation Committee**

Our compensation committee is composed of two directors, Alan Kazden and Ben Hu, M.D., each of whom is a non-employee member of our board of directors as defined in Rule 16b-3 under the Exchange Act. Alan Kazden is the chairman of the compensation committee. Our board of directors has determined that the composition of our compensation committee satisfies the applicable independence requirements under, and the functioning of our compensation committee complies with the applicable requirements of, Nasdaq listing rules and SEC rules and regulations. We intend to continue to evaluate and intend to comply with all future requirements applicable to our compensation committee. The principal duties and responsibilities of our compensation committee include:

- establishing and approving, and making recommendations to the board of directors regarding, performance goals and objectives relevant to the compensation of our chief executive officer, evaluating the performance of our chief executive officer in light of those goals and objectives and setting, or recommending to the full board of directors for approval, the chief executive officer's compensation, including incentive-based and equity-based compensation, based on that evaluation;
- setting the compensation of our other executive officers, based in part on recommendations of the chief executive officer;
- exercising administrative authority under our stock plans and employee benefit plans;
- establishing policies and making recommendations to our board of directors regarding director compensation;
- reviewing and discussing with management the compensation discussion and analysis that we may be required from time to time to include in SEC filings; and



- preparing a compensation committee report on executive compensation as may be required from time to time to be included in our annual proxy statements or annual reports on Form 10-K filed with the SEC.

### **Nominating and Corporate Governance Committee**

The nominating and corporate governance committee is composed of three directors, Alan Kazden, Rick Morad, and Ben Hu, M.D. Alan Kazden is the chairman of the nominating and corporate governance committee. Our board of directors has determined that the composition of our nominating and corporate governance committee satisfies the applicable independence requirements under, and the functioning of our nominating and corporate governance committee complies with the applicable requirements of, Nasdaq listing standards and SEC rules and regulations. We will continue to evaluate and will comply with all future requirements applicable to our nominating and corporate governance committee. The nominating and corporate governance committee's responsibilities include:

- assessing the need for new directors and identifying individuals qualified to become directors;
- recommending to the board of directors the persons to be nominated for election as directors and to each of the board's committees;

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- assessing individual director performance, participation and qualifications;
- developing and recommending to the board corporate governance principles;
- monitoring the effectiveness of the board and the quality of the relationship between management and the board; and
- overseeing an annual evaluation of the board's performance.

### *Board Leadership Structure*

Our corporate governance guidelines provide that, if the chairman of the board is a member of management or does not otherwise qualify as independent, the independent directors of the board may elect a lead director. The lead director's responsibilities will include, but not be limited to: presiding over all meetings of the board of directors at which the chairman is not present, including any executive sessions of the independent directors; approving board meeting schedules and agendas; and acting as the liaison between the independent directors and the chief executive officer and chairman of the board. Our corporate governance guidelines will further provide the flexibility for our board of directors to modify our leadership structure in the future as it deems appropriate. Mr. Rick Morad is the chairman of the board, and we have determined that he qualifies as an independent director.

### *Role of the Board in Risk Oversight*

One of the key functions of our board of directors is informed oversight of our risk management process. Our board of directors will not have a standing risk management committee but will rather administer this oversight function directly through our board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. Our audit committee also monitors compliance with legal and regulatory requirements. Our nominating and corporate governance committee will monitor the effectiveness of our corporate governance practices, including whether they are successful in preventing illegal or improper liability-creating conduct. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking. While each committee will be responsible for evaluating certain risks and overseeing the management of such risks, our entire board of directors will be regularly informed through committee reports about such risks.

### *Code of Business Conduct and Ethics for Employees, Executive Officers and Directors*

We have adopted a Code of Business Conduct and Ethics, or the code of conduct, applicable to all our employees, executive officers and directors. The code of conduct is available on our website at [www.nexalin.com](http://www.nexalin.com). The nominating and corporate governance committee of our board of directors will be responsible for overseeing the code of conduct and must approve any waivers of the code of conduct for employees, executive officers and directors. We expect that any amendments to the code of conduct, or any waivers of its requirements for any executive officer or director, will be disclosed on our website.

### *Compensation Committee Interlocks and Insider Participation*

None of our directors who currently serve as members of our compensation committee is or has at any time during the past year been, one of our officers or employees. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee of any other entity that has one or more of its executive officers serving on our board of directors or compensation committee.

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### *Limitation on Liability and Indemnification Matters*

Our amended and restated certificate of incorporation, and our amended and restated bylaws, limit our directors' liability, and may indemnify our directors and officers to the fullest extent permitted under Delaware General Corporation Law, or the DGCL. The DGCL provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for any:

- transaction from which the director derives an improper personal benefit;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or redemption of shares; or
- breach of a director's duty of loyalty to the corporation or its stockholders.

These limitations of liability do not apply to liabilities arising under federal securities laws and do not affect the availability of equitable remedies such as injunctive relief or recession.

The DGCL and our amended and restated bylaws provide that we will, in certain situations, indemnify our directors and officers and may indemnify other employees and other

agents, to the fullest extent permitted by law. Any indemnified person is also entitled, subject to certain limitations, to advancement, direct payment or reimbursement of reasonable expenses (including attorneys' fees and disbursements) in advance of the final disposition of the proceeding.

In addition, we have entered or will enter into indemnification agreements with our directors and officers. These indemnification agreements, among other things, require us to indemnify our directors and officers for certain expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of their services as a director or officer, or any other company or enterprise to which the person provides services at our request.

We also maintain a directors' and officers' insurance policy pursuant to which our directors and officers are insured against liability for actions taken in their capacities as directors and officers.

We believe that these provisions in our amended and restated certificate of incorporation and amended and restated bylaws, these indemnification agreements and this insurance are necessary to attract and retain qualified persons as directors and officers.

Insofar as indemnification of liabilities arising under the Securities Act of 1933, as amended, or the Securities Act, may be permitted to our board of directors, executive officers or persons controlling us pursuant to the foregoing provisions, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

## ITEM 11 EXECUTIVE AND DIRECTOR COMPENSATION

Our named executive officers for the year ended December 31, 2022, which consist of our principal executive officer and our other most highly compensated executive officers, were:

Mark White, our President and Chief Executive Officer  
Marilyn Elson, our Chief Financial Officer  
David Owens, M.D., our Chief Medical Officer  
Michael Nketiah, our Senior Vice President of Quality, Clinical and Regulatory

### Summary Compensation Table

The following table presents the compensation awarded to, earned by, or paid to our named executive officers, during the two (2) years ended December 31, 2022 and 2021.

Name and Principal Position	Year	Salary \$	Bonus \$	Stock Awards \$	Total \$
Mark White Chief Executive Officer	2021	175,000	5,000	404,132	584,132
	2022	191,292	-	-	191,292
Marilyn Elson <sup>(1)</sup> Chief Financial Officer	2021	-	-	-	-
	2022	345,000	-	-	345,000
David Owens, M.D. <sup>(2)</sup> Chief Medical Officer	2021	-	-	293,750	293,750
	2022	-	-	-	-
Michael Nketiah <sup>(3)</sup> Senior Vice-President of Quality, Clinical and Regulator	2021	-	-	-	-
	2022	32,080	-	-	32,080

(1) Marilyn Elson was appointed as our Chief Financial Officer on January 11, 2022. Ms. Elson has entered into an employment agreement with the Company. The agreement provides for a term of three years commencing as of January 1, 2022 at an annual salary of \$360,000 per annum. The compensation table does not include payments due to U.S. Asian, an entity which provides consulting services to the Company and of which Ms. Elson is a member.

(2) David Owens, M.D., Chief Medical Officer, has no 2022 compensation due to waiver of his 2022 compensation.

(3) Michael Nketiah was retained by the Company effective November 15, 2022 to serve as its Senior Vice President of Quality, Clinical and Regulatory. His compensation agreement with the Company provides for a base salary of \$250,000 per annum. The amount shown reflects his compensation received during the year ended December 31, 2022.

The Compensation Committee of the Board of Directors is discussing with the Company's Chief Executive Officer, Chief Medical Officer and Senior Vice President changes or additions to their compensation arrangements. It is expected that the base salary of our Chief Executive Officer will be increased. The compensation packages may include new bonus compensation arrangements which may include new stock-based compensation. The Compensation Committee is also considering making modifications to the compensation arrangements with its non-employee directors and members of the Board of Advisors. In order to make any definitive agreements with its officers or directors or employees generally, the Company will need to implement a stock-based plan in accordance with Nasdaq Stock markets rules, which include among other things, approval of any such plan by stockholders.

### Narrative to Summary Compensation Table

We review compensation annually for all employees, including our executives. In setting executive base salaries and bonuses and granting equity incentive awards, we consider compensation for comparable positions in the market, the historical compensation levels of our executives, individual performance as compared to our expectations and objectives, our desire to motivate our employees to achieve short- and long-term results that are in the best interests of our stockholders and a long-term commitment to our company. In addition, we have also engaged compensation consultants and take into consideration their assessments of our compensation.

The compensation committee of our board of directors has historically reviewed and made recommendations to our board of directors regarding our executives' compensation. Our compensation committee typically reviews and discusses management's proposed compensation with the chief executive officer for all executives other than the chief executive officer. Based on those discussions and its discretion, the compensation committee then recommends the compensation for each executive officer for approval by our board of directors. To date, our compensation committee has not adopted a peer group of companies for purposes of determining executive compensation.

On February 15, 2021, the Company entered into an employment agreement with Mark White to serve as Chief Executive Officer of the Company for a three-year term. Pursuant to the agreement, Mr. White is entitled to receive \$200,000 in annual compensation and is eligible to receive up to \$200,000 in additional cash and stock-based compensation upon achieving certain performance metrics. During the 2021 and 2022 years, Mr. White received cash compensation of \$180,000 and \$191,292 respectively. Additionally, on February 15, 2021, pursuant to the agreement, the Company issued shares of the Company's common stock in an amount representing two (2%) percent of the Company's issued and outstanding shares as of the effective date of the agreement, or 80,827 shares of the Company's common stock. Mr. White has waived the deficit amounts otherwise payable under his employment arrangements.

On February 15, 2021, the Company entered into an employment agreement with David Owens, M.D. to serve as Chief Medical Officer of the Company for a three-year term. Dr. Owens has provided services to the Company prior to the date of his employment agreement. For the 2021 year, Dr. Owens received compensation paid in shares of common stock in the amount of \$293,750. Pursuant to the agreement, Dr. Owens is entitled to receive \$150,000 in annual compensation payable by the issuance of Company common stock. He is also eligible to receive bonus compensation based upon achieving certain performance metrics. In March 2022, the Company entered into an amendment to the agreement with Dr. Owens to clarify certain matters related to his compensation. Dr. Owens has agreed that all shares issuable to him as compensation through December 31, 2021 (shares of common stock with a compensation value of \$293,750) have been issued and he has been paid in full all amounts due to him for his prior service through December 31, 2021. For determining the number of shares issuable to him for his 2022 services, the number of shares would be based upon offering price of the Company's Common Stock in our IPO. For the number of shares issuable during 2022 and 2023, the value shall equal, the average closing price of the Company's Common Stock for the 30 trading days prior to December 23, 2022. Dr. Owens has waived his 2022 compensation.

On November 15, 2022 the Company retained Michael Nketiah to serve as its Senior Vice President of Quality, Clinical and Regulatory. His compensation agreement with the Company provides for a base salary of \$250,000 per annum. For the year ended December 31, 2022, Mr. Nketiah received total compensation of \$32,080.

On January 11, 2022, the Company entered into an employment agreement with Marilyn Elson to serve as Chief Financial Officer of the Company for a three-year term. Pursuant to the agreement, Ms. Elson is entitled to receive \$360,000 in annual compensation that is payable to her in cash. For the year ended December 31, 2022, Ms. Elson received total compensation of \$345,000.

The Company (through its Board Compensation Committee) is in discussions with its Chief Executive Officer and Chief Medical Officer regarding potential changes to their compensation arrangements. These discussions may include modifications to the base salary and bonus arrangements which may include stock-based compensation. The Company expects to submit for shareholder approval, in accordance with NASDAQ Stock Market requirements, a stock-based compensation plan so that it can enter into new individual agreements with its executive officers and allow for stock based grants to employees, advisors and directors.

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#### *Annual Base Salary*

Base salaries for our executives are initially established through arm's length negotiation at the time the executive is hired, taking into account such executive's qualifications, experience, prior salary, the scope of his or her responsibilities and competitive market compensation paid by other companies for similar positions within the industry. Base salaries are to be reviewed annually in January by our compensation committee and approved by our board of directors in connection with our annual performance review process. Salaries may be adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience. In making decisions regarding salary increases, we may also confer with a compensation consultant or draw upon the experience of members of our board of directors with other companies. The 2022 and 2021 base salaries of our named executive officers are as follows:

Name	December 31,	
	2022 \$	2021 \$
Mark White <sup>(1)</sup>	200,000	200,000
David Owens, M.D. <sup>(2)</sup>	150,000	150,000
Marilyn Elson <sup>(3)</sup>	360,000	-
Michael Nketiah <sup>(4)</sup>	250,000	-

(1) During the 2022 year, Mr. White received cash compensation of \$191,292. During the 2021 year, he received cash compensation of \$180,000. Both amounts were less than the agreed upon cash compensation level in the agreement. Mr. White has agreed to waive any amounts which were not paid under his employment agreement for 2022 and 2021.

(2) On February 15, 2021, the Company entered into an employment agreement with David Owens, M.D. to serve as Chief Medical Officer of the Company for a three-year term. Dr. Owens was providing services to the Company prior to the date of his employment agreement. For the 2022 year, Dr. Owens received no compensation. For the 2021 year he received compensation paid in shares of common stock in the amount of \$293,750. In March 2022, we entered into an amendment of the agreement with Dr. Owens to clarify certain matters related to his compensation. Dr. Owens has agreed that all shares issuable to him as compensation or for any other amounts he may have been due or owed through December 31, 2021 (shares of common stock with a compensation value of \$293,750) have been issued and no further amounts are due. The stated amounts in the table above reflects the employment agreement amount. Amounts payable to Dr. Owens are paid in shares of common stock. Dr. Owens waived his compensation for fiscal 2022.

(3) Ms. Elson is entitled to a base salary of \$360,000 per annum. For the year ended December 31, 2022, based on less than a full year of employment, she received total compensation of \$345,000.

(4) Mr. Nketiah is entitled to a base salary of \$250,000 per annum. For the year ended December 31, 2022, based on less than a full year of employment, he received total compensation of \$32,080.

#### *Health and Welfare Benefits*

We adopted a company medical benefit plan in fiscal year 2023 and all employees are eligible to participate. The Company believes that the plan is usual and customary in nature to provide for health coverage for all employees.

#### *Non-Employee Director Compensation*

Each non-employee director elected to our board of directors receives shares of our common stock equal to \$35,000 per annum. Mr. Morad has received an aggregate of 21,000 shares of common stock for his services during 2019, 2020 and 2021. Dr. Hu and Mr. Kazden have each received an aggregate of 14,000 shares of common stock for their two years of service during 2020 and 2021. In August 2022, Mr. Morad, Dr. Hu and Mr. Kazden were each issued 5,833 shares of the Company's stock for their 2022 services.

Our policy of compensating our non-employee directors is intended to provide a total compensation package that enables us to attract and retain qualified and experienced individuals to serve as directors and to align our directors' interests with those of our stockholders. The Board of Directors is considering new arrangements for compensation of directors and advisors. No definitive plans have been determined, but it is expected that compensation will include a stock-based provision. The Company expects to request stockholder approval for a broad-based equity plan at its annual meeting to be held in the second or third quarter of 2023.

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## ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth the beneficial ownership of our 7,286,562 shares of our common stock outstanding as of March 22, 2023 for:

- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our current executive officers and directors as a group.

We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. For purposes of this table, we have not included or given effect to any warrants, including warrants to be sold in this offering, or any underlying shares of common stock.

The address for persons listed in the table is c/o Nexalin Technology, Inc., 1776 Yorktown, Suite 550, Houston, TX 77056.

### *Directors, Executive Officers and 5% Shareholders*

<b>Name of Beneficial Owner</b>	<b>Number of Shares Beneficially Owned</b>	<b>Percentage of Shares Beneficially Owned</b>
Marilyn Elson and Leonard Osser	835,244 <sup>(2)</sup>	11.46%
Mark White	309,127 <sup>(1)(3)</sup>	4.24%
Rick Morad	170,126 <sup>(3)(4)</sup>	2.33%
Benjamin Hu	165,636 <sup>(3)(5)</sup>	2.27%
David Owens, MD	141,174 <sup>(3)(6)</sup>	1.94%
Alan Kazden	83,131 <sup>(3)(7)</sup>	1.14%
Michael Nketiah	-	-
<b>All Directors, Executive Officer and Affiliates as a Group (7 People)</b>	<b>1,704,438</b>	<b>23.38%</b>

(1) Mark White is Chief Executive Officer and a director of the Company. Includes shares owned by Mr. White in his individual name and IICOM Strategic LLC, an entity controlled by Mr. White. Mr. White has voting and dispositive power over the shares held by IICOM Strategic LLC.

(2) Leonard Osser and Marilyn Elson, Chief Financial Officer of the Company, are husband and wife and deemed to have beneficial ownership of each other's holdings. Each has joint voting and dispositive control in the securities owned by each other. The calculation of the number of shares issued to U.S. Asian Consulting, Group LLC that sustains their equity at 15% of issued and outstanding shares included 300,000 shares held in escrow for the benefit of Wider, which are to be released upon the completion of Wider's clinical trials. Under the consulting agreement with U.S. Asian Consulting Group LLC, the parties agreed that in consideration for deferring payments and for terminating previously agreed upon ant-dilution rights, U.S. Asian would be entitled to 15% of the issued and outstanding shares of the Company until our public offering completed in September 2022.

(3) Director of the Company.

(4) Includes shares owned by Mr. Morad individually and through the Rick Morad Family Trust, and his individual retirement account

(5) Includes shares owned by Mr. Hu individually and through the Benjamin V. Hu American Estate and Equity Trust Custodian FBO Benjamin V Hu, over which shares Mr. Hu has voting and dispositive power. Also includes shares owned by Mr. Hu's spouse through the Amy N. Hu American Estate and Equity Trust Company Custodian FBO Amy N. Lun Hu IRA, over which shares Mr. Hu's spouse has voting and dispositive power.

(6) Dr. Owens is the Chief Medical Officer and a Director of the Company. Includes shares owned by Dr. Owens individually and through LTB Investment Holdings, LLC, an entity controlled by Dr. Owens. Dr. Owens has voting and dispositive control over all of such shares.

(7) Mr. Kazden is a director of the Company. Includes shares owned by the Alan and Natalie Kazden Family Trust. Mr. Kazden has voting and dispositive control over all of such shares.

### *Description Of Capital Stock*

The following description of our capital stock and certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries. You should also refer to the amended and restated certificate of incorporation and bylaws, which are filed as exhibits to the registration statement for our IPO.

#### **General**

Our authorized capital consists of shares of common stock, par value \$0.001 per share. Under our Certificate of Incorporation, as amended to date, we are authorized to issue 100,000,000 shares of common stock, \$0.001 par value per share.

#### **Common Stock**

As of March 22, 2023, we had 7,286,562 shares of common stock outstanding, held of record by approximately 900 stockholders.

#### Voting Rights

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders. The affirmative vote of holders of at least 66% of the voting power of all of the then-outstanding shares of capital stock, voting as a single class, will be required to amend certain provisions of our amended and restated certificate of incorporation, including provisions relating to amending our amended and restated bylaws, the classified board, the size of our board, removal of directors, director liability, vacancies on our board, special meetings, stockholder notices, actions by written consent and exclusive forum.

#### Dividends

Holders of our common stock are entitled to receive ratably any dividends that our board of directors may declare out of funds legally available for that purpose.

#### Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in all assets remaining after payment of liabilities.

#### Rights and Preferences

Holders of our common stock have no pre-emptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate in the future.

#### Fully Paid and Nonassessable

All outstanding shares of our common stock are fully paid and non-assessable.

### **Warrants Issued in Our Initial Public Offering**

The following summary of certain terms and provisions of the warrants included in our initial public offering competed in September, 2022, and is subject to and qualified in its entirety by the provisions of the form of the warrants agent agreement filed as an exhibit to our registration statement filed in connection with our initial public offering.

#### Exercisability

The warrants are exercisable at any time after their original issuance and at any time up to the date that is three (3) years after their original issuance (September 20, 2025). The warrants are exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares purchased upon such exercise (except in the case of a cashless exercise as discussed below).

#### Exercise Limitation

A holder will not have the right to exercise any portion of the warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days following notice from the holder to us.

#### Exercise Price

The exercise price per share of common stock purchasable upon exercise of the warrants is \$4.15 per share. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

#### Cashless Exercise

If, at any time during the term of the warrants, the issuance of shares of common stock upon exercise of the warrants is not covered by an effective registration statement, the holder is permitted to effect a cashless exercise of the warrants (in whole or in part) by having the holder deliver to us a duly executed exercise notice, cancelling a portion of the warrant in payment of the purchase price payable in respect of the number of shares of common stock purchased upon such exercise.

#### Failure to Timely Deliver Shares

If we fail for any reason to deliver to the holder the shares subject to an exercise by the date that is the earlier of (i) two (2) trading days and (ii) the number of trading days that is the standard settlement period on our primary trading market as in effect on the date of delivery of the exercise notice, we must pay to the holder, in cash, as liquidated damages and not as a penalty, for each \$1,000 of shares subject to such exercise (based on the daily volume weighted average price of our shares of common stock on the date of the applicable exercise notice), \$10 per trading day (increasing to \$20 per trading day on the fifth (5<sup>th</sup>) trading day after such liquidated damages begin to accrue) for each trading day after such date until such shares are delivered or the holder rescinds such exercise. In addition, if after such date the holder is required by its broker to purchase (in an open market transaction or otherwise) or the holder's brokerage firm otherwise purchases, shares of common stock to deliver in satisfaction of a sale by the holder of the shares which the holder anticipated receiving upon such exercise, then we shall (A) pay in cash to the holder the amount, if any, by which (x) the holder's total purchase price (including brokerage commissions, if any) for the shares of common stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of shares that we were required to deliver to the holder in connection with the exercise at issue times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the holder, either reinstate the portion of the warrant and equivalent number of shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the holder the number of shares of common stock that would have been issued had we timely complied with our exercise and delivery obligations.

#### Exchange Listing

Our warrants are listed on Nasdaq under the symbol "NXLIW."

#### Redemption

We may redeem the outstanding warrants, in whole and not in part, at a price of \$0.01 per warrant:

- at any time while the warrants are exercisable,
- upon a minimum of 30 days' prior written notice of redemption,
- if, and only if, the last sales price of our common stock equals or exceeds \$12.45 per share for any 20 trading days within a 30 trading day period ending three (3) business

days before we send the notice of redemption, and

- if, and only if, there is a current registration statement in effect with respect to the shares of common stock underlying such warrants at the time of redemption and for the entire 30-day trading period referred to above and continuing each day thereafter until the date of redemption.

If the foregoing conditions are satisfied and we issue a notice of redemption, each warrant holder can exercise his, her or its warrant prior to the scheduled redemption date. However, the price of our common stock may fall below the \$12.45 redemption trigger price, as well as the \$4.15 warrant exercise price, after the redemption notice is issued.

The redemption criteria for our warrants have been established at a price which is intended to provide warrant holders a reasonable premium to the initial exercise price and provide a sufficient differential between the then-prevailing share price and the warrant exercise price so that if the share price declines as a result of our redemption call, the redemption will not cause the share price to drop below the exercise price of the warrants.

#### Rights as a Stockholder

Except as otherwise provided in the warrants or by virtue of such holder's ownership of shares of our common stock, the holder of a warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the warrant.

#### Governing Law

The Warrants and the Warrant Agency Agreement are governed by New York law. Our warrant agreement with our transfer agent, which govern the terms of the warrants, will provide that, subject to applicable law, (i) any action, proceeding or claim against us or the warrant agent arising out of or relating in any way to the warrant agreement shall be brought and enforced in the courts of the State of New York or the United States District Court for the Southern District of New York, and (ii) that we and the warrant agent irrevocably submit to such jurisdiction, which jurisdiction shall be the exclusive forum for any such action, proceeding or claim. We and the warrant agent will waive any objection to such exclusive jurisdiction and that such courts represent an inconvenient forum.

Notwithstanding the foregoing, this exclusive forum provision shall not apply to suits brought to enforce a duty or liability created by the Exchange Act, any other claim for which the federal courts have exclusive jurisdiction or any complaint asserting a cause of action arising under the Securities Act against us or any of our directors, officers, other employees or agents. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. In addition, shareholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

#### **Transfer Agent and Registrar**

Our transfer agent and registrar for our common stock and warrants is Continental Stock Transfer & Trust Company.

### **ITEM 13 CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS AND DIRECTOR INDEPENDENCE**

The following is a description of transactions since our inception to which we have been a participant in which the amount involved exceeded or will exceed \$120,000, and in which any of our directors, executive officers or holders of more than 5% of our share capital, or any members of their immediate family, had or will have a direct or indirect material interest, other than compensation arrangements which are described under the section titled "Executive and Director Compensation."

#### *Joint Venture*

In September 2018, we entered into an agreement with Wider, pursuant to which we and Wider shall form the Joint Venture. Wider has an experienced medical technology team in China and when formed, the Joint Venture will design and implement a comprehensive business model and distribution plan for our devices in China, Hong Kong, Macau and Taiwan. In May 2019 we entered into a separate agreement with Wider authorizing it to act as a distributor of our devices pending completion of the potential Joint Venture. We do not pay Wider any commissions or distributor related fees; it derives profit from its markup of devices it sells.

In March 2022, we entered into a second supplement to the Joint Venture agreement with Wider, whereby the parties confirmed that the Joint Venture had not yet been established and is subject to further review and analysis of regulatory issues in China and the United States, trade and political issues between the two countries and potential changes in the use and market for the Company's products and technology. Pursuant to the second supplement, the parties agreed to use their commercial efforts to complete documentation by September 30, 2022. In light of general economic conditions in China and the United States and the continued impact of regulatory issues in China and the United States and trade and political issues between the two countries, the parties determined to further extend the time frame to complete establishment of the joint venture to September 30, 2023 and entered into a supplement 3 to the Joint Venture Agreement to memorialize such extension. The parties intend to continue to work together to complete the establishment prior to such extended time.

During 2022, we sold Gen-2 devices in China through Wider which agreed to act as a distributor on a limited basis pursuant to a separate agreement entered into in May 2019, pending formation of the Joint Venture. We do not pay Wider any commissions or distributor related fees; it derives profit from its markup of devices it sells.

We will own 50% of the Joint Venture when and if it is established. Additionally, under the terms of the Joint Venture agreements, Wider will receive a one-eighth equity position in our company at a valuation of \$40 million, one-third of which has been issued (which equalled an aggregate of 150,000 shares of Common Stock) and the balance of which is to be issued upon completion of the four clinical trials and at the time the potential Joint Venture is established and is fully funded by Wider.

#### *U.S. Asian Consulting Group, LLC*

On May 9, 2018, the Company entered into a five-year consulting agreement with U.S. Asian Consulting Group, LLC ("U.S. Asian"). In March 2021 the Company agreed to extend the consulting agreement for an additional period of eight years upon the closing of our initial public offering. The two members of U.S. Asian are shareholders in the Company, with Marilyn Elson having been appointed Chief Financial Officer of the Company on January 11, 2022. Pursuant to the consulting agreement, U.S. Asian provides consulting services to the Company with regards to, among other things, corporate development and financing arrangements. The Company is to pay U.S. Asian \$10,000 per month for services rendered and, on October 24, 2018, the Company issued 249,750 shares of the Company's common stock to U.S. Asian. The Company recorded consulting expenses related to the consulting agreement of \$120,000 and \$120,000 for the years ended December 31, 2022 and 2021, respectively, on the Company's statements of operations. For the years ended December 31, 2022 and 2021, U.S. Asian was owed \$260,000 and \$299,320, respectively, for accrued and unpaid services and expenses. We utilized \$237,419 of the proceeds of our IPO to repay a portion the outstanding amount due to U.S. Asian.

Pursuant to the consulting agreement, U.S. Asian was originally entitled to anti-dilution protection with respect to its share percentage ownership in the Company whereas U.S.

Asian's security holdings, during the term of the consulting agreement, would remain at 10% of the Company's total number of issued and outstanding shares of the Company's common stock, on a fully diluted basis. In March 2021, the Company entered into an agreement with U.S. Asian pursuant to which U.S. Asian waived and relinquished any rights of protection against dilution afforded to it, provided such dilution results from a transaction that (i) imputes a pre-money valuation to the Company of not less than \$7 million, (ii) raises not less than \$7 million, and (iii) imputes a post-money valuation to the Company of not less than \$25 million. In exchange for the waiver and relinquishment of such rights, the Company issued shares of the Company's common stock in an amount sufficient for U.S. Asian (together with its owners) to own an aggregate amount of fifteen (15%) percent of the Company's issued and outstanding shares of common stock as of the date of issuance. On June 22, 2021, the Company issued 304,570 shares of common stock in satisfaction of the waiver. On November 29, 2021 and in August of 2022, the Company issued an additional 217,500 and 17,699 respectively shares of common stock to U.S. Asian in satisfaction of the waiver.

Under our agreements with U.S. Asian Consulting Group LLC, U.S. Asian was granted a right to appoint one director to our Board of Directors. To date, U.S. Asian has not exercised this right.

Our principle executive office is located at 1776 Yorktown, Suite 550, Houston, Texas 77056. Under ASC 842 "Leases", we have two separate sub-leases (through Icom Strategic Inc. controlled and owned by our Chief Executive Officer) totaling approximately 4,000 square feet of office space under operating leases. Our lease payments totaled approximately \$48,000 in 2021. Management and supporting staff are hosted at this location. Our lease payments for fiscal year 2022 were \$54,000. Our lease costs for 2023 will also be \$54,000 for the year. The sub-leases are due to expire in 2024. Pursuant to the sublease, we pay the third-party landlord (not the sub landlord) all direct and indirect rent costs under the primary lease directly for the leased premises. No additional payments are made to the Chief Executive Officer or the entity controlled by him.

#### *Loans and Notes Payable*

On October 19, 2018, the Company issued an on demand promissory note payable with the Company's Chairman of the Board for \$10,000 with interest to begin accruing on January 1, 2020 at 5% per annum. On September 28, 2022, the Company's Chairman of the Board waived the accrued interest of \$2,718 which is reflected as Additional Paid in Capital. Total interest expense on this note was \$369 and \$1,448 for the years ended December 31, 2022 and 2021, respectively. The loan was paid in full in 2022.

On November 1, 2021, the Company received \$200,000 from the Company's Chief Executive Officer. The loan has a principal of \$200,000, an interest rate of 9%, and a maturity date of the earlier of (i) October 31, 2022 or (ii) the date of the consummation of our IPO. Total interest expense on this note was \$18,000 and \$3,000 for years December 31, 2022 and 2021. There was \$200,000 outstanding at both December 31, 2022 and 2021. The loan principal was paid in full on March 17, 2023.

#### *Related Person Transaction Policy*

Prior to our IPO, we did not have a formal policy regarding approval of transactions with related parties. We created and adopted a Code of Ethics which includes a written related person transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. The related person transaction policy is part of our Code of Ethics, a copy of which was filed as an exhibit to the registration statement for our IPO and is available on our website.

For purposes of this policy, a related person transaction is a transaction, arrangement or relationship or any series of similar transactions, arrangements or relationships, in which we and any related person are, were or will be participants in which the amount involved exceeds \$120,000. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. A related person is any executive officer, director or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or any transaction that was not initially identified as a related person transaction prior to consummation, our management must present information regarding the related person transaction to our audit committee, or, if audit committee approval would be inappropriate, to another independent body of our board of directors, for review, consideration and approval or ratification.

The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each director, executive officer and, to the extent feasible, significant stockholder to enable us to identify any existing or potential related-person transactions and to effectuate the terms of the policy. In addition, under our code of business conduct (Code of Ethics), our employees and directors have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest. In considering related person transactions, our audit committee, or another independent body of our board of directors, will take into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event that the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy requires that, in determining whether to approve, ratify or reject a related person transaction, our audit committee, or other independent body of our board of directors, must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our shareholders, as our audit committee, or other independent body of our board of directors, determines in the good faith exercise of its discretion.

#### **ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

Our consolidated financial statements as of December 31, 2022 and for the year then ended, have been included herein in reliance upon the report of Marcum LLP, independent registered public accounting firm, appearing elsewhere herein.

Our consolidated financial statements as of December 31, 2021 and for the years then ended, have been included herein in reliance upon the report of Friedman, LLP, independent registered public accounting firm, appearing elsewhere herein.

#### *Principal Accountant Fees and Services*

The Audit Committee of the Board of Directors of our Company selected Marcum LLP as its independent registered public accounting firm for the fiscal year ended December 31, 2022. During fiscal 2022, the audit services that Marcum provided consisted of examination of financial statements, services relative to filings with the SEC. The following table presents the total fees for professional audit and non-audit services rendered by our independent registered public accounting firms for the fiscal years ended December 31, 2022 and 2021, and fees for other services rendered by our independent registered public accounting firm during those periods. The fees to Friedman LLP in 2022 and 2021 were \$76,250 and \$110,000, respectively. The fees to Marcum LLP were \$70,000 in 2022.

	Year Ended December 31,	
	2022	2021
Audit Fees <sup>(1)</sup>	\$ 146,250	\$ 110,000
Audit-Related Fees <sup>(2)</sup>	\$	\$
Tax Fees <sup>(3)</sup>	\$	\$
All Other Fees <sup>(4)</sup>	\$	\$
Total	<u>\$ 146,250</u>	<u>\$ 110,000</u>

(1) "Audit Fees" consist of fees for professional services rendered for the audit of the Company's annual financial statements, review of the interim financial statements included in quarterly reports, and services that are normally provided by the Company's independent registered public accounting firm in connection with statutory and regulatory filings, including registration statements filed with the Securities and Exchange Commission. All audit fees for 2021 related to Friedman LLP services, while audit fees for 2022 relate to services provided by both Friedman LLP and Marcum LLP.

(2) "Audit-Related Fees" consist of fees for services that are traditionally performed by the independent registered public accounting firm, including fees billed or accrued primarily for employee benefit plan audits and other attestation services.

(3) "Tax Fees" consist of fees for professional services rendered for tax compliance, tax advice and tax planning.

(4) "All Other Fees" consist of fees for those services not captured in the audit, audit-related and tax categories. The Company generally does not request such services from the independent auditors.

Our Audit Committee has determined that the services provided by our independent registered public accounting firm and the fees paid to them for such services has not compromised the independence of our independent registered public accounting firm.

#### *Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services*

Consistent with SEC policies regarding auditor independence, the Audit Committee has responsibility for appointing, setting compensation and overseeing the work of the independent registered public accounting firm. In recognition of this responsibility, the Audit Committee has established a policy to pre-approve all audit and permissible non-audit services provided by the independent registered public accounting firm. Prior to engagement of the independent registered public accounting firm for the next year's audit, management will submit a detailed description of the audit and permissible non-audit services expected to be rendered during that year for each of four categories of services provided by the independent registered public accounting firm to the Audit Committee for approval. The four categories of services provided by the independent registered public accounting firm are as defined in the footnotes to the fee table set forth above. In addition, management will also provide to the Audit Committee for its approval a fee proposal for the services proposed to be rendered by the independent registered public accounting firm. Prior to the engagement of the independent registered public accounting firm, the Audit Committee will approve both the description of audit and permissible non-audit services proposed to be rendered by the independent registered public accounting firm and the budget for all such services. The fees are budgeted, and the Audit Committee requires the independent registered public accounting firm and management to report actual fees versus the budget periodically throughout the year by category of service. During the year, circumstances may arise when it may become necessary to engage the independent registered public accounting firm for additional services not contemplated in the original pre-approval. In those instances, the Audit Committee requires separate pre-approval before engaging the independent registered public accounting firm. To ensure prompt handling of unexpected matters, the Audit Committee may delegate pre-approval authority to one or more of its members. The member to whom such authority is delegated must report any pre-approval decisions to the Audit Committee at its next scheduled meeting.

## PART IV

### ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(a) Exhibits.

Exhibit Number	Description of Document
1.1**	<a href="#">Underwriting Agreement dated as of September 15, 2022 between the Registrant and Maxim Group LLC</a>
3.1*	<a href="#">Certificate of Incorporation, as amended and as currently in effect.</a>
3.2*	<a href="#">Amended and Restated Bylaws.</a>
4.1*	<a href="#">Form of Specimen stock certificate evidencing shares of common stock.</a>
4.2*	<a href="#">Warrant Agreement between the Company and Continental Stock Transfer and Trust company as warrant agent dated as of September 16, 2022</a>
4.3*	<a href="#">Form of Warrant Certificate (filed as part of Exhibit 4.2)</a>
10.1*	<a href="#">Potential Joint Venture Agreement between the Company and Wider Come Limited, and Supplement thereto, dated as of September 21, 2018, as supplemented by Supplement Number 1.</a>
10.2*	<a href="#">Employment Agreement between the Company and Mark White dated as of February 15, 2021.</a>
10.3*	<a href="#">Agreement between the Company and David Owens, M.D. dated as of February 15, 2021</a>
10.4*	<a href="#">Quality Assurance Agreement between the Company and Apical Instruments dated December 31, 2020.</a>
10.5*	<a href="#">Advisor Agreement with Leonard Osser dated as of December 22, 2021.</a>
10.6*	<a href="#">Advisor Agreement with Tucker Anderson dated as of December 24, 2021.</a>
10.7*	<a href="#">Advisor Agreement with Gian Domenico Trombetta dated December 24, 2021.</a>
10.8*	<a href="#">Employment Agreement between the Company and Marilyn Elson dated as of January 11, 2022</a>
10.9*	<a href="#">Amendment and Deferral Agreement dated as of March 30, 2022 to Consulting Agreement between the Company and US Asian Consulting Group LLC</a>
10.10*	<a href="#">Supplement Number 2 to potential Joint Venture Agreement dated as of March 1, 2022 between the Company and Wider Come Limited.</a>
10.11*	<a href="#">Amendment to Employment Agreement with David Owens, M.D.</a>
10.12*	<a href="#">Form of Lock-Up Agreement.</a>
10.13*	<a href="#">Consulting Agreement dated as of May 9, 2018 as amended between the Company and US Asian Consulting Group, LLC, as amended on January 2, 2019 and March 4, 2021</a>



10.14*	<a href="#">Promissory Note in favor Mark White dated as of November 1, 2021, as amended</a>
10.15*	<a href="#">Distribution Authorization Agreement dated as of May 1, 2019 with Wider Come Limited.</a>
23.1*	<a href="#">Consent of Friedman LLP, independent registered public accounting firm</a>
31.1****	<a href="#">Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.</a>
31.2****	<a href="#">Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended</a>
32.1****	<a href="#">Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
32.2****	<a href="#">Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>
99.1*	<a href="#">Code of Ethics</a>
99.2*	<a href="#">Audit Committee Charter</a>
99.3*	<a href="#">Compensation Committee Charter</a>
99.4*	<a href="#">Nominating and Corporate Governance Committee Charter</a>

\* Previously filed as an exhibit to Form S-1 as declared effective by the SEC on September 15, 2022 (SEC File Number 333-261989).

\*\* Previously filed as an exhibit to Form 8-K as filed with the SEC on September 20, 2022

\*\*\* Previously filed as an exhibit to Form 8-K/A as filed with the SEC on September 20, 2022.

\*\*\*\* Filed as an exhibit to this Form 10-K.

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## ITEM 16. FORM 10-K SUMMARY

None.

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## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

### NEXALIN TECHNOLOGY, INC.

By: /s/ Mark White

Mark White  
Chief Executive Officer  
(Principal Executive Officer)  
Date: March 24, 2023

By: /s/ Marilyn Elson

Marilyn Elson  
Chief Financial Officer  
(Principal Financial and Accounting Officer)  
Date: March 24, 2023

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

By: /s/ Mark White

Mark White  
Chief Executive Officer  
(Principal Executive Officer)  
Date: March 24, 2023

By: /s/ Marilyn Elson

Marilyn Elson  
Chief Financial Officer  
(Principal Financial and Accounting Officer)  
Date: March 24, 2023

By: /s/ Rick Morad

Rick Morad  
Director  
Date: March 24, 2023

By: /s/ Alan Kazden

Alan Kazden  
Director  
Date: March 24, 2023

By: /s/ Ben Hu, M.D.

Ben Hu, M.D.  
Director  
Date: March 24, 2023

By: /s/ David Owens

David Owens  
Director

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA****NEXALIN TECHNOLOGY, INC.  
CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2022 AND 2021****TABLE OF CONTENTS**

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Stockholders and Board of Directors of  
Nexalin Technology, Inc. and Subsidiary

**Opinion on the Consolidated Financial Statements**

We have audited the accompanying consolidated balance sheet of Nexalin Technology, Inc. and Subsidiary (the "Company") as of December 31, 2021, and the related consolidated statements of operations, stockholders' deficit, and cash flows for the year ended December 31, 2021, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021, and the results of its operations and its cash flows for the year ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

**Basis for Opinion**

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provide a reasonable basis for our opinion.

/s/ Friedman llp

Friedman llp

We served as the Company's auditor from 2020-2022.

Marlton, New Jersey  
April 7, 2022

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To the Stockholders and Board of Directors of  
Nexalin Technology, Inc. and Subsidiary

**Opinion on the Consolidated Financial Statements**

We have audited the accompanying consolidated balance sheet of Nexalin Technology, Inc. and Subsidiary (the "Company") as of December 31, 2022, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit) and cash flows for the year ended December 31, 2022, and the related notes (collectively referred to

as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022, and the results of its operations and its cash flows for the year ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

### Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor since 2020 (such date takes into account the acquisition of certain assets of Friedman LLP by Marcum LLP effective September 1, 2022.)

Marlton, New Jersey

March 24, 2023

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## NEXALIN TECHNOLOGY, INC. AND SUBSIDIARY CONSOLIDATED BALANCE SHEETS

	December 31,	
	2022	2021
<b>ASSETS</b>		
<b>Current Assets:</b>		
Cash and cash equivalents	\$ 162,743	\$ 661,778
Short-term investments	6,831,192	-
Accounts receivable	4,875	16,303
Inventory	154,370	31,410
Prepaid expenses and other current assets	272,282	43,168
<b>Total Current Assets</b>	<b>7,425,462</b>	<b>752,659</b>
ROU Asset	6,171	-
Equipment, net of accumulated depreciation of \$2,181 and \$29,862, respectively	503	1,039
<b>Total Assets</b>	<b>\$ 7,432,136</b>	<b>\$ 753,698</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
<b>Current Liabilities:</b>		
Accounts payable (Includes related party of \$260,000 and \$399,320, respectively)	\$ 658,367	\$ 843,794
Accrued expenses	539,822	611,795
Lease liability, current portion	50,797	40,845
Loan payable - shareholder	-	37,200
Loan payable - officer	200,000	200,000
Note payable	500,000	500,000
Deferred revenue	-	130,000
<b>Total Current Liabilities</b>	<b>1,948,986</b>	<b>2,363,634</b>
<b>Long-term Liabilities:</b>		
Lease liability, net of current portion	4,463	49,089
PPP Loan payable	-	22,916
<b>Total Liabilities</b>	<b>1,953,449</b>	<b>2,435,639</b>
<b>Commitments and Contingencies (Note 8)</b>		
<b>Stockholders' Equity (Deficit):</b>		
Common stock, \$0.001 par value; 100,000,000 shares authorized; 7,286,562 and 4,879,923 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	7,287	4,880
Accumulated other comprehensive income	36,313	-
Additional paid in capital	77,824,427	69,004,703
Accumulated deficit	(72,389,340)	(70,691,524)
<b>Total Stockholders' Equity (Deficit)</b>	<b>5,478,687</b>	<b>(1,681,941)</b>
<b>Total Liabilities and Stockholders' Equity (Deficit)</b>	<b>\$ 7,432,136</b>	<b>\$ 753,698</b>

The accompanying notes are an integral part of these consolidated financial statements.

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**NEXALIN TECHNOLOGY, INC. AND SUBSIDIARY**  
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**

	Year Ended December 31,	
	2022	2021
Revenues, net (Includes related party of \$1,183,367 and \$26,132 for the year ended December 31, 2022 and December 31, 2021, respectively)	\$ 1,321,357	\$ 144,065
Cost of revenues	363,212	21,442
Gross profit	<u>958,145</u>	<u>122,623</u>
Operating expenses		
Professional fees	605,329	697,063
Salaries and benefits	694,108	228,738
Selling, general and administrative	1,491,739	5,215,423
Total operating expenses	<u>2,791,176</u>	<u>6,141,224</u>
Loss from operations	<u>(1,833,031)</u>	<u>(6,018,601)</u>
Other income (expense), net:		
Interest expense, net	(59,382)	(82,319)
Other income	171,681	-
Forgiveness of PPP Loan	22,916	22,916
Total other income (expense), net	<u>135,215</u>	<u>(59,403)</u>
Net loss	<u>(1,697,816)</u>	<u>(6,078,004)</u>
Other comprehensive income:		
Unrealized gain from short-term investments	36,313	-
Comprehensive loss	<u>\$ (1,661,503)</u>	<u>\$ (6,078,004)</u>
Net loss per share attributable to common stockholders - Basic and Diluted	\$ (0.30)	\$ (1.43)
Weighted Average Shares Outstanding - Basic and Diluted	5,572,402	4,256,360

The accompanying notes are an integral part of these consolidated financial statements.

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**NEXALIN TECHNOLOGY, INC. AND SUBSIDIARY**  
**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)**

	Common Stock		Accumulated Other Comprehensive Gain (Loss) on ST Investments	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount				
<b>Balance at January 1, 2021</b>	3,695,464	\$ 3,695	\$ -	\$ 63,019,495	\$ (64,613,520)	\$ (1,590,330)
Stock issued for cash	297,099	297	-	1,433,470	-	1,433,767
Stock compensation	865,861	865	-	4,464,670	-	4,465,535
Shares issued for conversion of debt	10,507	11	-	38,614	-	38,625
Shares issued for exercise of warrants	8,492	9	-	35,957	-	35,966
Shares issued for inducement	2,500	3	-	12,497	-	12,500
Net loss	-	-	-	-	(6,078,004)	(6,078,004)
<b>Balance as of December 31, 2021</b>	<u>4,879,923</u>	<u>\$ 4,880</u>	<u>\$ -</u>	<u>\$ 69,004,703</u>	<u>\$ (70,691,524)</u>	<u>\$ (1,681,941)</u>
Stock issued for cash	2,315,850	2,316	-	8,542,954	-	8,545,270
Stock compensation	90,789	91	-	270,579	-	270,670
Related party foregone interest	-	-	-	2,718	-	2,718
Warrants issued for cash	-	-	-	3,473	-	3,473
Other comprehensive gain	-	-	36,313	-	-	36,313
Net loss	-	-	-	-	(1,697,816)	(1,697,816)
<b>Balance as of December 31, 2022</b>	<u>7,286,562</u>	<u>\$ 7,287</u>	<u>\$ 36,313</u>	<u>\$ 77,824,427</u>	<u>\$ (72,389,340)</u>	<u>\$ 5,478,687</u>

The accompanying notes are an integral part of these consolidated financial statements.

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**NEXALIN TECHNOLOGY, INC. AND SUBSIDIARY**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Years Ended December 31,	
	2022	2021
<b>Cash flows from operating activities:</b>		
Net Loss	(1,697,816)	(6,078,004)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Bad debt expense	11,175	-
Stock compensation	270,670	4,478,035
Forgiveness of interest expense	(168,361)	-
Forgiveness of PPP loan	(22,916)	-
Depreciation	535	537
Non-cash lease expense	5,188	-
Write off of inventory	19,892	-
<b>Changes in operating assets and liabilities:</b>		
Accounts receivable	253	(9,704)
Prepaid assets	(229,114)	(33,974)
Inventory	(142,852)	(8,754)
Accounts payable - related party	(139,320)	-
Accounts payable	(46,107)	382,633
Accrued expenses	99,107	99,413
Deferred revenue	(130,000)	130,000
Lease liability	(46,033)	(36,973)
Net cash used in operating activities	<u>(2,215,699)</u>	<u>(1,076,791)</u>
<b>Cash flows from investing activities:</b>		
Purchase of short-term investments	(6,794,879)	-
Net cash used in investing activities	<u>(6,794,879)</u>	<u>-</u>
<b>Cash flows from financing activities:</b>		
Sale of common stock for cash, net of financing fees	8,545,270	1,433,767
Proceeds from exercise of warrants	3,473	35,966
Payments on loan payable - shareholder	(37,200)	(9,600)
Proceeds from notes payable – officer	-	200,000
Net cash provided by financing activities	<u>8,511,543</u>	<u>1,660,133</u>
Net decrease in cash and cash equivalents	(499,035)	583,342
Cash and cash equivalents - beginning of year	661,778	78,436
Cash and cash equivalents - end of year	<u>162,743</u>	<u>661,778</u>
<b>Non-cash investing and financing activities:</b>		
Unrealized gain on short-term investments	36,313	-
Conversion of debt and accrued interest into common stock	-	38,625
ROU asset and lease liability recorded	11,359	-
Forgiveness of interest expense	168,361	-
Forgiveness of PPP loan	22,916	-

The accompanying notes are an integral part of these consolidated financial statements.

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**NEXALIN TECHNOLOGY, INC. AND SUBSIDIARY  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 1 — NATURE OF THE ORGANIZATION AND BUSINESS**

*Corporate History*

Nexalin Technology, Inc. ("NV Nexalin") was formed on October 19, 2010 as a Nevada corporation. The Company's principal offices are located at 1776 Yorktown, Suite 550, Houston, Texas 77056.

On September 6, 2019, Neuro-Health International, Inc. ("Neuro-Health"), a Nevada corporation, a wholly owned subsidiary of NV Nexalin, was formed. Neuro-Health had no activity from December 6, 2019 (Inception) through December 31, 2022.

On November 22, 2021, NV Nexalin entered into an Agreement and Plan of Merger (the "Merger Agreement") with Nexalin Technology, Inc., a Delaware corporation ("Nexalin", or the "Company"). Pursuant to the Merger Agreement, NV Nexalin merged with and into Nexalin with all shareholders of NV Nexalin receiving one common share of Nexalin in exchange for twenty shares of NV Nexalin held at the time of the Merger Agreement. NV Nexalin treated the transaction as a corporate reorganization with the historical consolidated financial statements of NV Nexalin becoming the historical consolidated financial statements of Nexalin. Nexalin had nominal assets and liabilities and did not conduct any operations prior to the reorganization other than its incorporation. NV Nexalin has retroactively applied the 20-for-1 exchange, effective on November 22, 2021, to share and per share amounts on the audited consolidated financial statements for the years ended December 31, 2022 and 2021. NV Nexalin's authorized shares of common stock were not affected as a result of the Merger Agreement. As a result of the Merger Agreement, NV Nexalin was dissolved, and Neuro-Health became a subsidiary of Nexalin. The Company completed its initial public offering on September 16, 2022.

The initial public offering consisted of 2,315,000 units consisting of 2,315,000 shares of its Common Stock and 2,315,000 accompanying warrants to purchase up to 2,315,000 shares of common stock. Each share of common stock is being sold together with one Warrant, each to purchase one share of common stock with an exercise price of \$4.15 per share at a combined offering price of \$4.15, for gross proceeds of \$9,607,250, before deducting underwriting discounts and offering expenses. In addition, Nexalin granted the underwriters a 45-day option to purchase up to an additional 347,250 shares of common stock and/or Warrants to purchase up to 347,250 shares of common stock to cover over-allotments at the initial public offering price, less the underwriting discount. The underwriters exercised their option to purchase 347,250 warrants for net proceeds of \$3,473.

The registration statement on Form S-1 (File No. 333-261989) was filed with the Securities and Exchange Commission ("SEC"), which became effective on September 15, 2022. A

final prospectus relating to the offering was filed with the SEC and is available on the SEC's website at <http://www.sec.gov>.

Our shares and warrants began trading on the Nasdaq Capital Market tier of the Nasdaq Stock Market ("Nasdaq") on September 16, 2022, under the symbols "NXL" and "NXLW", respectively.

Throughout this report, the terms "Nexalin," "our," "we," "us," and the "Company" refer to Nexalin Technology, Inc.

### *Business Overview*

We design and develop innovative neurostimulation products to uniquely and effectively help combat the ongoing global mental health epidemic. We developed an easy-to-administer medical device — referred to as Generation 1 or Gen-1 — that utilizes bioelectronic medical technology to treat anxiety and insomnia, without the need for drugs or psychotherapy. Our original Gen-1 devices are cranial electrotherapy stimulation (CES) devices that emit waveform at 4 milliamps during treatment and are presently classified by the U.S. Food and Drug Administration ("FDA") as a Class II device.

While we continue providing services to medical professionals to support patients' use of the Gen-1 devices which were in operation prior to December 2019, we are not making new sales or new marketing efforts of Gen-1 devices. We continue to derive revenue from devices which we sold or leased prior to the FDA's December 2019 reclassification announcements. This revenue consists of monthly licensing fees and payments for the sale of electrodes. We have suspended marketing efforts for new sales of devices related to the Gen-1 device for treatment of anxiety and insomnia in the United States until the Nexalin regulatory team makes a decision on a new 510(k) application at 4 milliamps based on FDA comments expected to be received in April 2023.

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We have designed and developed a new advanced wave form technology to be emitted at 15 milliamps through new and improved medical devices referred to as Generation 2 or Gen-2 and Generation 3 or Gen-3. Gen-2 is a clinical use device with a modern enclosure to emit the new 15 milliamp advanced waveform. Gen-3 is a new patient headset that will be prescribed by licensed medical professionals in a virtual clinic setting similar to existing Tele-health platforms. Preliminary data provided by the University of California San Diego supports the safety of utilizing our 15 milliamp waveform technology, however the determination of safety and efficacy of medical devices in the United States is subject to clearance by the FDA.

Additionally, we are currently designing clinical trial strategies for the use of Gen-3 for the treatment of substance use disorders including opiate, cocaine, and alcohol abuse. Recently the Gen-2 device was tested in pilot trials in China for the treatment of Alzheimer's disease, and dementia. Continued pilot testing for Alzheimer's and dementia is planned in China in 2023.

### *Emerging Growth Company*

The Company is an "emerging growth company," as defined in Section 2(a) of the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), and it may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in its periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and approval of any golden parachute payments not previously approved. Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. The Company has elected not to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public or private companies, the Company, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of the Company's consolidated financial statements with another public company which is neither an emerging growth company, nor an emerging growth company which has opted out of using the extended transition period, difficult or impossible because of the potential differences in accounting standards used.

### *Risks and Uncertainties*

Management continues to evaluate the impact of the COVID-19 pandemic and Russia-Ukraine war on the economy and the capital markets and has concluded that, while it is reasonably possible that such events could have negative effects on the Company's financial position and results of its operations, the specific impacts are not readily determinable as of the date of these consolidated financial statements. The consolidated financial statements do not include any adjustments that might result from the outcome of these uncertainties.

The current challenging economic climate may lead to adverse changes in cash flows, working capital levels and/or debt balances, which may also have a direct impact on the Company's operating results and financial position in the future. The ultimate duration and magnitude of the impact and the efficacy of government interventions on the economy has and may continue to indirectly impact the Company because of its current dependence upon its distributor relationship with Wider Come Limited. Wider Come Limited acts as a distributor for the Company's devices in China and Asia. Because of significant restrictions imposed by the Chinese government during the COVID-19 pandemic through calendar year 2022, Wider's ability to market and sell the Company's devices has been negatively impacted, resulting in decreased revenue to the Company. Patients and salespeople are restricted in their movements resulting in a significant slowdown in the medical and other sectors. Significant efforts and funds expended by our Chinese distributor has led to regulatory approval in China in both depression and insomnia thus far which has allowed for sales of our devices in China in 2022. The extent of future impact will depend on future developments, including future activities by the Chinese government and other possible events which are highly uncertain and not in the Company's control, including new information which may emerge concerning the spread and severity of COVID19, or any of its variants, and actions taken to address its impact, among others. The repercussions of this health crisis could have a material adverse effect on the Company's business, financial condition, liquidity and operating results.

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## **NOTE 2 — LIQUIDITY**

The accompanying audited consolidated financial statements have been prepared on the basis that the Company will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business. At December 31, 2022, the Company had a significant accumulated deficit of approximately \$72.4 million. For the year ended December 31, 2022, the Company had a loss from operations of approximately \$1.8 million and negative cash flows used in operations of approximately \$2.2 million. While the Company had a working capital surplus as of December 31, 2022 of approximately \$5.5 million, the Company's operating activities consume most of its cash resources.

The Company expects to continue to incur operating losses as it executes its development plans, as well as undertaking other potential strategic and business development initiatives through 2023 and through the twelve months from the date of this report. In addition, the Company has had and expects to have negative cash flows from operations, at least into the near future. The Company previously funded these losses primarily through the sale of equity and issuance of convertible notes. The accompanying audited

consolidated financial statements do not include any adjustments that might be necessary should the Company be unable to continue as a going concern.

The Company's ability to continue as a going concern will be dependent upon its ability to execute on its business plan, including the ability to generate revenue from the proposed joint venture and obtain U.S. approval for the sale of its devices in the United States, and the Company's ability to raise additional capital. Although no assurances can be given as to the Company's ability to deliver on its revenue plans or that unforeseen expenses may arise, management has evaluated the significance of the conditions as of December 31, 2022 and has concluded that due to the receipt of the net proceeds from the completion of the Initial Public Offering, the Company has sufficient cash and short-term investments on hand to satisfy its anticipated cash requirements for the next twelve months from the issuance of these financial statements.

### NOTE 3 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND NEW ACCOUNTING STANDARDS

#### *Basis of Presentation*

The accompanying audited consolidated financial statements have been prepared in accordance with Generally Accepted Accounting Principles in the United States ("GAAP"). In the opinion of management, such financial information includes all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation of the Company's financial position and the operating results and cash flows. Operating results for the years ended December 31, 2022 and 2021 are not necessarily indicative of the results that may be expected for future years or for any other subsequent interim period. Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with GAAP have been omitted pursuant to the rules of the U.S. Securities and Exchange Commission (the "SEC").

#### *Principles of Consolidation*

The consolidated financial statements include the accounts of Nexalin and its wholly owned subsidiary Neuro-Health. Intercompany accounts and transactions have been eliminated in consolidation.

#### *Use of Estimates*

The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, equity-based transactions, revenue and expenses and disclosure of contingent liabilities at the date of the consolidated financial statements. The Company bases its estimates and assumptions on historical experience, known or expected trends and various other assumptions that it believes to be reasonable. As future events and their effects cannot be determined with precision, actual results could differ from these estimates which may cause the Company's future results to be affected.

#### *Revenue*

The Company recognizes revenue when its performance obligations with its customers have been satisfied. At contract inception, the Company determines if the contract is within the scope of Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers*, and then evaluates the contract using the following five steps: (1) identify the contract with the customer; (2) identify the performance obligations; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations; and (5) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only recognizes revenue to the extent that it is probable that a significant revenue reversal will not occur in a future period.

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The Company has existing licensing and treatment fee agreements with its customers for the use of the Nexalin Device in their practices. These agreements generally have terms of one year with automatic renewal if certain requirements are met and amounts due per these agreements are billed monthly. The Company also sells products related to the provision of services. The Company sells its Devices in China to its acting distributor and sells products relating to the use of the Devices. The Company has a Royalty Agreement whereby the manufacturer of the Company's electrodes will pay a royalty to the Company for a three-year period beginning January 1, 2022. The amount of the Royalty is equal to 20% of the amount that the manufacturer invoices to the acting distributor for the sale of the electrodes.

#### **Revenue Streams**

We derive revenues from our license agreements by charging a monthly licensing fee for the duration of the agreement. We derive revenues from equipment by selling additional individual electrodes to customers for use with the Nexalin Device. We receive revenue from the sale in China of our Devices to our distributor and from the sale of products relating to the use of those Devices. We derive revenue as a royalty fee from the China-based manufacturer for electrodes ordered in connection with our China sales.

#### **Performance Obligations**

Management identified that subsequent licensing revenue has one performance obligation. That performance obligation is satisfied if the licensing contract remains valid and is not terminated. The licensing revenue is invoiced monthly and is recognized at a point in time in which the invoice is sent to the customer.

Management identified that the Company's equipment and Device revenue has one performance obligation. That performance obligation is satisfied when the equipment and Devices are shipped. The Company recognizes revenue at a point in time in which the equipment and Devices are shipped to the customer. The Company does not offer a warranty on the equipment or Devices.

Management identified that treatment fee revenue has one performance obligation. The performance obligation is satisfied upon the completion of individual treatments on patients by customers.

Management identified that royalty revenue has one performance obligation. The performance obligation is satisfied at the time the Electrode manufacturer notifies the Company that it has invoiced the distributor for the sale to the distributor.

#### **Practical Expedients**

As part of ASC 606, the Company has adopted several practical expedients including:

- **Significant Financing Component** — the Company does not adjust the promised amount of consideration for the effects of a significant financing component since the Company expects, at contract inception, that the period between when the Company transfers promised goods or services to the customer and when the customer pays for that service will be one year or less.
- **Unsatisfied Performance Obligations** — for all performance obligations related to contracts with a duration of less than one year, the Company has elected to apply the optional exemption provided in ASC Topic 606 and therefore, is not required to disclose the aggregate amount of the transaction price allocated to performance obligations that are unsatisfied or partially unsatisfied at the end of the reporting period.
- **Shipping and Handling Activities** — the Company elected to account for shipping and handling activities as a fulfillment cost rather than as a separate performance obligation.

- Right to invoice — the Company has a right to consideration from a customer in an amount that corresponds directly with the value to the customer of the Company's performance completed to date; the Company may recognize revenue in the amount to which the entity has a right to invoice.

## Disaggregated Revenues

### Major Revenue Streams

	Years Ended December 31,	
	2022	2021
Device Sales	\$ 1,164,500	\$ 25,000
Licensing Fee	79,188	102,910
Royalty Fee	24,479	-
Equipment	26,778	15,218
Other	26,412	937
Total	\$ 1,321,357	\$ 144,065

### Major Geographic Locations

	Years Ended December 31,	
	2022	2021
U.S. Sales	\$ 113,541	\$ 117,933
China Sales	1,207,816	26,132
Total	\$ 1,321,357	\$ 144,065

### Contract Modifications

There were no contract modifications during the years ended December 31, 2022 and 2021. Contract modifications are not routine in the performance of the Company's contracts.

### Deferred Revenue

The Company receives payment for equipment and devices in advance of shipping. The Company recognizes the revenue as being earned upon shipment. Deferred revenue of \$- and \$130,000 was recognized as of December 31, 2022 and 2021, respectively.

	Deferred Revenue
Outstanding at January 1, 2021	\$ -
Recognized	130,000
Outstanding at January 1, 2022	130,000
Recognized	442,000
Transferred to revenue	(572,000)
	\$ -

### Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less at the time of purchase be cash equivalents. Cash and cash equivalents held at financial institutions may at times exceed insured amounts. The Company believes it mitigates such risk by investing in or through, as well as maintaining cash balances with, with major financial institutions.

### Short-Term Investments

The appropriate classification of marketable securities is determined at the time of purchase and evaluated as of each reporting balance sheet date. Investments in marketable debt and equity securities classified as available-for-sale are reported at fair value. Fair value is determined using quoted market prices in active markets for identical assets or liabilities or quoted prices for similar assets or liabilities or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Changes in fair value that are considered temporary are reported net of tax in accumulated other comprehensive income. Realized gains and losses, amortization of premiums and discounts and interest and dividends earned are included in other income (expense), net. For declines in the fair values of equity securities that are considered other-than-temporary, impairment losses are charged to other income (expense), net. The Company considers available evidence in evaluating potential impairments of its investments, including the duration and extent to which fair value is less than cost. There were no deemed permanent impairments at December 31, 2022 or 2021.

### Accounts Receivable

Accounts receivables are reported at their outstanding unpaid principal balances, net of allowances for doubtful accounts. The Company periodically assesses its accounts and other receivables for collectability on a specific identification basis. The Company provides for allowances for doubtful receivables based on management's estimate of uncollectible amounts considering age, collection history, and any other factors considered appropriate. Payments are generally due within 30 days of invoice. The Company writes off accounts receivable against the allowance for doubtful accounts when a balance is determined to be uncollectible. During the year ended December 31, 2022 and 2021, the Company wrote off \$11,175 and \$-, respectively, in accounts receivable. The Company did not record an allowance for doubtful accounts as of December 31, 2022 and 2021, respectively.

### Inventory



Inventory consists of finished goods and components stated at the lower of cost or net realizable value (NRV) with cost determined on a first-in first-out basis. The Company reviews the composition of inventory at each reporting period in order to identify obsolete, quantities in excess of demand, or otherwise non-saleable items. At December 31, 2022 the Company wrote down inventory in the amount of \$19,892 to its NRV.

#### Equipment

Equipment is recorded at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the related assets, generally five years.

Maintenance and repairs are charged to expense as incurred. The Company capitalizes costs attributable to the betterment of property and equipment when such betterment enhances the functionality of the asset or extends the useful life of the asset. Should an asset be disposed of before the end of its useful life, the cost and accumulated depreciation at that date is removed from the consolidated balance sheets, with the resulting gain or loss, if any, reflected in operations in that period.

#### Advertising and Marketing Costs

The Company expenses advertising and marketing costs as they are incurred. Advertising and marketing expenses were \$21,149 and \$35,487 for the years ended December 31, 2022 and 2021, respectively. All advertising and marketing expenses are recorded in selling, general and administrative expenses on the audited consolidated statements of operations.

#### Income Taxes

The Company accounts for income taxes pursuant to the asset and liability method which requires the recognition of deferred income tax assets and liabilities related to the expected future tax consequences arising from temporary differences between the carrying amounts and tax bases of assets and liabilities based on enacted statutory tax rates applicable to the periods in which the temporary differences are expected to reverse. Any effects of changes in income tax rates or laws are included in income tax expense in the period of enactment.

The Company records valuation allowances against deferred tax assets when it is more likely than not that all or a portion of a deferred tax asset will not be realized. At December 31, 2022 and 2021, the Company had a full valuation allowance applied against its net tax assets

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#### Fair Value Measurements

As defined in ASC 820, *Fair Value Measurements and Disclosures*, fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (exit price). The Company utilizes market data or assumptions that market participants would use in pricing the asset or liability, including assumptions about risk and the risks inherent in the inputs to the valuation technique. These inputs can be readily observable, market corroborated, or generally unobservable. ASC 820 establishes a fair value hierarchy that prioritizes the inputs used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1 measurement) and the lowest priority to unobservable inputs (level 3 measurement). This fair value measurement framework applies at both initial and subsequent measurement.

- Level 1: Quoted prices are available in active markets for identical assets or liabilities as of the reporting date. Active markets are those in which transactions for the asset or liability occur in sufficient frequency and volume to provide pricing information on an ongoing basis.
- Level 2: Pricing inputs are other than quoted prices in active markets included in Level 1, which are either directly or indirectly observable as of the reported date. Level 2 includes those financial instruments that are valued using models or other valuation methodologies. These models are primarily industry-standard models that consider various assumptions, including quoted forward prices for commodities, time value, volatility factors and current market and contractual prices for the underlying instruments, as well as other relevant economic measures. Substantially all these assumptions are observable in the marketplace throughout the full term of the instrument, can be derived from observable data or are supported by observable levels at which transactions are executed in the marketplace.
- Level 3: Pricing inputs include significant inputs that are generally less observable from objective sources. These inputs may be used with internally developed methodologies that result in management's best estimate of fair value. The significant unobservable inputs used in the fair value measurement for nonrecurring fair value measurements of long-lived assets include pricing models, discounted cash flow methodologies and similar techniques.

#### Fair Value of Financial Instruments

The carrying value of cash, short-term investments, accounts receivable, inventory, prepaids, accounts payable and accrued expenses, and other current liabilities approximate their fair values based on the short-term maturity of these instruments. The carrying amount of the loans payable approximates the estimated fair value for this financial instrument as management believes that such debt and interest payable on the note approximates the Company's incremental borrowing rate.

The following table summarizes the amortized cost, unrealized gains and the fair value at December 31, 2022 and 2021

	Amortized Cost	Unrealized Gain	Fair Value
<b>December 31, 2022</b>			
Short-term investments	\$ 6,794,879	\$ 36,313	\$ 6,831,192
Total December 31, 2022	\$ 6,749,879	\$ 36,313	\$ 6,831,192
<b>December 31, 2021</b>			
Short-term investments	\$ -	\$ -	\$ -
Total December 31, 2021	\$ -	\$ -	\$ -

The following table provides the carrying value and fair value of the Company's financial assets measured at fair value as of December 31, 2022 and 2021.

	Carrying Value	Level 1	Level 2	Level 3
<b>December 31, 2022</b>				
U.S. Treasury Notes	\$ 6,831,192	\$ 6,831,192	\$ -	\$ -
<b>December 31, 2021</b>				
U.S. Treasury Notes	\$ -	\$ -	\$ -	\$ -

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### Net Loss per Common Share

Net loss per common share is computed by dividing the net loss by the weighted average number of common shares outstanding during the period. The dilutive effect, if any, of warrants is calculated using the treasury stock method. All outstanding convertible notes, if any, are considered common stock at the beginning of the period or at the time of issuance, if later, pursuant to the if-converted method. Since the effect of common stock equivalents is anti-dilutive with respect to losses, the warrants have been excluded from the Company's computation of net loss per common share for the years ended December 31, 2022 and 2021.

The following table summarizes the securities that would be excluded from the diluted per share calculation because the effect of including these potential shares was antidilutive due to the Company's net loss position even though the exercise price could be less than the most recent fair value of the common shares:

	Years Ended December 31,	
	2022	2021
Warrants	2,662,250	21,600
Total	2,662,250	21,600

### Stock-Based Compensation

The Company applies the provisions of ASC 718, *Compensation — Stock Compensation* ("ASC 718"), which requires the measurement and recognition of compensation expense for all stock-based awards made to employees, including employee stock options, in the statements of operations.

For stock options issued to employees and members of the board of directors for their services, the Company estimates the grant date fair value of each option using the Black-Scholes option pricing model. The use of the Black-Scholes option pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected life of the option, risk-free interest rates and expected dividend yields of the common stock. For awards subject to service-based vesting conditions, including those with a graded vesting schedule, the Company recognizes stock-based compensation expense equal to the grant date fair value of stock options on a straight-line basis over the requisite service period, which is generally the vesting term. Forfeitures are recorded as they are incurred as opposed to being estimated at the time of grant and revised.

Pursuant to ASU 2018-07 *Compensation — Stock Compensation* (Topic 718): *Improvements to Non-employee Share-Based Payment Accounting*, the Company accounts for stock options and restricted shares issued to non-employees for their services in accordance with ASC 718. The Company uses valuation methods and assumptions to value the stock options that are in line with the process for valuing employee stock options noted above.

### Warrant Accounting

The Company does not use derivative instruments to hedge exposures to cash flow, market, or foreign currency risks. The Company evaluates all its financial instruments, including issued private and public warrants, to determine if such instruments are derivatives or contain features that qualify as embedded derivatives, pursuant to ASC Topic 480, *Distinguishing Liabilities from Equity*, and ASC Topic 815-40, *Derivatives and Hedging: Contracts in Entity's Own Equity* ("ASC 815-40"). The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is assessed as part of this evaluation. During the reporting periods the Public Warrants were outstanding, they were precluded from liability classification, being equity-classified.

### Research and Development

Research and development costs are charged to operations as incurred. For the years ended December 31, 2022 and 2021, the Company recorded approximately \$511,000 and \$139,000 respectively, in selling, general and administrative expenses on the audited consolidated statements of operations.

### Leases

A lease is defined as an agreement that conveys the right to control the use of identified property, plant or equipment (right of use asset or "ROU asset") for a period in exchange for consideration. The Company accounts for its leases in accordance with ASC 842, *Leases*, which requires that an ROU asset identified in a lease be recorded as a noncurrent asset with a related liability. The Company does not record ROU assets for those agreements of a twelve-month duration or less. The Company recognized a ROU asset and corresponding lease liability on its balance sheets related to its office lease agreement. See Note 9 — Leases for further discussion, including the impact on the Company's audited consolidated financial statements and related disclosures.

ROU assets include any initial direct costs and prepaid lease payments and exclude any lease incentives. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. The lease terms may include options to extend or terminate the lease if it is reasonably certain that the Company will exercise that option.

### Paycheck Protection Program

The Company's policy was to account for the PPP loan as debt. The Company continued to record the loan as debt until either (1) the loan was partially or entirely forgiven and the Company had been legally released, at which point the amount forgiven would be recorded as income or (2) the Company paid off the loan. During 2022 and 2021 the Company's outstanding PPP loans were forgiven (see Note 6).

### Recent Accounting Pronouncements

In November 2021, the FASB issued ASU 2021-10, *Government Assistance* (Topic 832). ASU 2021-10 and its amendments will be effective for the Company for interim and annual periods in fiscal years beginning after December 15, 2021. The Company believes the disclosure requirements related to governmental assistance have been appropriately made, specifically pertaining to PPP Loans that were forgiven by the government in 2021. The total impact of the forgiveness on the consolidated financial statements was immaterial.

In February 2020, the FASB issued ASU 2020-02, *Financial Instruments—Credit Losses* (Topic 326) and *Leases* (Topic 842) - *Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 119 and Update to SEC Section on Effective Date Related to Accounting Standards Update No. 2016-02, Leases* (Topic 842), which amends the effective date of the original pronouncement for smaller reporting companies. ASU 2016-13 and its amendments will be effective for the Company for interim and annual periods in fiscal years beginning after December 15, 2022. The Company believes the adoption will modify the way the Company analyzes financial instruments, but it does not anticipate a material impact on results of operations. The Company is in the process of determining the effects adoption will have on its audited consolidated financial statements.

All other newly issued but not yet effective accounting pronouncements have been deemed to be not applicable or immaterial to the Company.

**NOTE 4 — ACCRUED EXPENSES**

Accrued expenses consist of the following amounts:

	Years Ended December 31,	
	2022	2021
Accrued interest	\$ 111,501	\$ 232,952
Accrued - other	2,321	42,843
Accrued settlement liabilities	336,000	336,000
Accrued research and development expense	90,000	-
Total	\$ 539,822	\$ 611,795

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**NOTE 5 — NON-CONSOLIDATED JOINT VENTURE AND RELATED PARTY TRANSACTIONS***Potential Joint Venture*

On December 21, 2018, the Company entered into the first of a series of agreements providing for the establishment of a joint venture ("JV") agreement (the "JV Agreement") with Wider Come Limited, a China company ("Wider") for the purpose of marketing, sale and distribution of the Company's proprietary devices for the treatment of (i) anxiety, depression and insomnia ("ADP") and (ii) Alzheimer's and dementia ("AD") in the applicable territories. Wider has an experienced medical technology team in China and when formed, the JV will design and implement a comprehensive business model and distribution plan for our devices in China, Hong Kong, Macau and Taiwan. The JV will be formed following the completion of certain funding, clinical study, and publication milestones, which Wider has agreed to undertake but not yet completed, as well as resolution of potential regulatory concerns in China. Following its formation, the JV will design and implement a comprehensive business model and distribution plan for our devices in China, Hong Kong, Macau and Taiwan.

As originally contemplated, each of the parties to the JV would hold a 50% interest in the equity, profits and losses, shareholder voting, management control and rights to use production capacity of the facility. The Company will provide a global exclusive technology license for ADI treatment to the JV and Wider will contribute funding for the design and execution of Company approved clinical studies. The Company will also provide the JV with a license for exclusive distribution of its technology for the treatment of ADI in additional territories. As originally contemplated the JV, if completed, will be controlled by an equally represented Board of Directors in which neither entity has sole decision-making ability over day-to-day or significant operational decisions. The parties may determine to alter the equity interest or board composition of the Joint Venture or other economic terms as they move closer to its implementation.

As of December 31, 2022, the JV has not been established.

On May 22, 2019, the Company entered into a supplementary agreement to the JV Agreement (the "Supplementary Agreement"). At the time of the May 2019 Supplementary Agreement, the parties desired to expand the scope of the JV to include and address the pain management opportunities for our devices and technology. Pursuant to the Supplementary Agreement, Wider was to fund the JV within thirty days of execution of the JV Agreement with \$600,000 in cash to be used for clinical trials and other activities related to pain management utilization of our devices and technology in China. Within thirty days of the funding, the Company was to issue 5% of the Company in non-diluted common stock to Wider's shareholders. As of the date of this report the JV has yet to be formally established and therefore the \$600,000 has not been funded. Further, the parties have determined not to proceed with the pain management scope of the JV and have decided to terminate the May 2019 Supplementary Agreement. The parties may elect to proceed with a similar arrangement in the future.

On April 6, 2020, the Company entered into a three-year service agreement with Wider, pursuant to which Wider agreed to perform clinical trials associated with the formation of the JV. In consideration, the Company and certain designated Wider shareholders entered into stock issuance agreements for the issuance of 450,000 shares of the Company's common stock, and simultaneously with the execution of this service agreement, Wider contributed \$200,000 to the Company. During the year ended December 31, 2020, the Company issued 150,000 shares to affiliates of Wider in satisfaction of the obligation. The fair value of the 150,000 shares issued (less the contributed \$200,000 in cash) resulted in a charge to stock-based compensation of \$550,000 and was recorded in selling, general and administrative expenses on the statement of operations. The remaining 300,000 shares will be issued in accordance with the following schedule upon Wider's successful completion of the following milestones (i) 50% upon successful completion of the fourth of four clinical trials pursuant to the terms and conditions of the Service Agreements and (ii) 50% upon all four trials being submitted for publication in international medical journals satisfactory to the Company. As of December 31, 2022, these milestones have not been met.

In March 2022, we entered into a second supplement to the JV Agreement with Wider, whereby the parties confirmed that the JV had not yet been established and is subject to further review and analysis of regulatory issues in China and the United States, trade and political issues between the two countries and potential changes in the use and market for the Company's products and technology. Pursuant to the second supplement, the parties agreed to use their commercial efforts to complete documentation by December 30, 2022. Wider has continued its work with respect to undertaking and establishing clinical trials. In light of general economic conditions in China and the United States and the continued impact of regulatory issues in China and the United States and trade and political issues between the two countries, the parties determined to further extend the time frame to complete establishment of the JV to December 30, 2023 and entered into a supplement 3 to the JV Agreement to memorialize such extension. The parties intend to continue to work together to complete the establishment prior to such extended time, however, the ramifications of the continued COVID pandemic, especially in China, and the Chinese government's regulatory approach to the pandemic have adversely affected Wider's ability to distribute our current products. As a result, the JV may be further delayed or we and Wider may determine to re-structure the business terms (which changes may include timing and the scope of the intended operations and trial studies) of the proposed JV.

During the years ended December 31, 2022 and 2021, the Company recorded \$1,183,367 and \$26,132 in revenue, respectively, from Wider

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*U.S. Asian Consulting Group, LLC*

On May 9, 2018, the Company entered into a five-year consulting agreement with U.S. Asian Consulting Group, LLC ("U.S. Asian"). The two members of U.S. Asian are shareholders in the Company and include Marilyn Elson who is the Chief Financial Officer of the Company. Pursuant to the consulting agreement, U.S. Asian will provide consulting services to the Company with regard to, among other things, corporate development and financing arrangements. The Company is to pay U.S. Asian \$10,000 per month for services rendered and, on October 24, 2018, the Company issued 249,750 shares of the Company's common stock to U.S. Asian. The Company recorded consulting expenses related to the consulting agreement of \$120,000 in each of the years ended December 31, 2022 and 2021 on the Company's audited consolidated statements of operations. At December 31, 2022 and 2021, U.S. Asian was owed \$260,000 and \$399,320, respectively, for accrued and unpaid services and expenses. These amounts are included in accounts payable. A payment of \$250,000 was made to U.S. Asian on March 17, 2023.

On December 22, 2021, the Company entered into a one-year agreement with Leonard Osser to serve on the Company's Board of Advisors. The agreement may be, but has not yet been, extended for an additional one-year term upon agreement of both parties. As consideration Mr. Osser was entitled to \$80,000 in shares of the Company's common stock and payment was waived by Mr. Osser.

On January 11, 2022, the Company entered into an employment agreement with Marilyn Elson to serve as Chief Financial Officer of the Company for a three-year term with an option for the Company and Ms. Elson to extend the term for an additional two years. Ms. Elson is the spouse of Leonard Osser.

#### *Loan Payable – Officer*

On November 1, 2021, the Company received \$200,000 as a loan from the Company's Chief Executive Officer. The loan has a principal of \$200,000, an interest rate of 9%, and a maturity date of the earlier of (i) October 31, 2022 or (ii) the date of the consummation of the initial public offering. Total interest expense on this note was \$18,000 and \$3,000 for the years ended December 31, 2022 and 2021 respectively. There was \$200,000 outstanding each of December 31, 2022 and 2021. With respect to the amount owed under this loan, the Company's Chief Executive Officer has agreed to defer payment until March 15, 2023. A payment of \$200,000 was made on March 17, 2023 in satisfaction of the loan principal.

#### *Promissory Notes*

On October 19, 2018, the Company issued an on demand promissory note payable with the Company's Chairman of the Board for \$10,000 with interest to begin accruing on January 1, 2020 at 5% per annum. On September 28, 2022, the Company's Chairman of the Board waived the accrued interest of \$2,718 which is reflected as Additional Paid in Capital in the consolidated statements of changes in stockholders' equity (deficit). The note was paid in full as of December 31, 2022. Total interest expense on this note was \$369 and \$1,488 for the years ended December 31, 2022 and 2021, respectively.

Our principle executive office is located at 1776 Yorktown, Suite 550, Houston, Texas 77056. Under ASC 842 "Leases", we have two separate sub-leases (through Ilcom Strategic Inc. controlled and owned by our Chief Executive Officer) totalling approximately 4,000 square feet of office space under operating leases. Our lease payments totalled approximately \$48,000 in 2021. Management and supporting staff are hosted at this location. Our lease payments for fiscal year 2022 were \$54,000. Our lease costs for 2023 will also be \$54,000 for the year. The sub-leases are due to expire in 2024. Pursuant to the sublease, we pay the third party landlord (not the sub landlord) all direct and indirect rent costs under the primary lease directly for the leased premises. No additional payments are made to the Chief Executive Officer or the entity controlled by him.

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## **NOTE 6 — LOANS PAYABLE**

### *Loans Payable*

On October 25, 2018, the Company entered in a promissory note payable with an accredited investor for \$50,000 due on October 25, 2019. Pursuant to the note, the maturity date was extended to October 25, 2020. The promissory note bears interest at 100% per annum and the note holder was issued shares of the Company's common stock in lieu of interest. On October 7, 2020, the Company entered into a Letter of Agreement Addendum with the note holder, whereas the Company agreed to make ten monthly principal payments beginning November 1, 2020 with the full principal amount to be paid in full by August 31, 2021. In addition, if the full principal amount was not paid in full by August 31, 2021 the Company was to and did issue an additional 2,500 shares of common stock to the noteholder. On November 11, 2021, the Company entered into a Second Letter of Agreement Addendum with the note holder, whereas the Company agreed to continue making monthly payments beginning on December 1, 2021. Total interest expense related to this note was \$15,643 and \$50,000 for the years ended December 31, 2022 and 2021, respectively. During the years ended December 31, 2022 and 2021, the Company paid \$27,200 and \$9,600, respectively, in cash towards the outstanding principal. The amount outstanding at December 31, 2021, was \$27,200. On September 28, 2022, the note holder waived the accrued interest of \$168,245 and the amount was included in "other income (expense), net" on the consolidated statement of operations. The note was paid in full as of December 31, 2022.

On February 4, 2021, under the U.S. Small Business Administration's Paycheck Protection Program, the Company entered into a second note payable with a financial institution for \$22,916 at an interest rate of 1% per annum and a maturity date of February 4, 2026. Pursuant to the note, principal and interest payments are deferred for ten months, which, at any time during the ten months the Company may apply for loan forgiveness. The Company applied for loan forgiveness on a timely basis, and as of December 31, 2022, the total amount of \$22,916 has been forgiven.

### *Legacy Ventures International, Inc.*

On December 11, 2017, the Company issued a promissory note (the "Promissory Note") in favour of Legacy Ventures International, Inc. ("Legacy") as part of a commercial transaction with Legacy that was never consummated. The Promissory Note was issued in the original principal amount of \$500,000, with interest at 4% per annum and a maturity date of December 31, 2017. As of December 31, 2022, this promissory note is in default. The Company recorded \$20,000 of interest expense in each of the years ended December 31, 2022 and 2021. The amount outstanding at December 31, 2022 and 2021 was \$500,000.

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## **NOTE 7 — STOCKHOLDERS' EQUITY (DEFICIT)**

### *Issuance of Common Stock*

During the year ended December 31, 2021, the Company issued an aggregate of 297,099 shares of common stock to various investors for cash proceeds of \$1,433,767.

During the year ended December 31, 2021, the Company issued an aggregate of 865,861 shares of common stock with a fair value of \$5.00 per share to various consultants for services rendered in lieu of cash for a compensation charge of \$4,465,535.

During the year ended December 31, 2021, the company issued an aggregate of 10,507 shares of common stock to various note holders for the conversion of debt.

During the year ended December 31, 2021, the company issued an aggregate of 8,492 shares of common stock to various investors for the conversion of warrants.

During the year ended December 31, 2021, the Company issued an aggregate of 2,500 shares of common stock with a fair value of \$5.00 per share to a note holder as inducement.

During the year ended December 31, 2022, the Company issued 2,315,850 shares of common stock to investors for net proceeds of \$8,545,270.

During the year ended December 31, 2022, the Company issued 90,789 shares of common stock for services in lieu of cash of which 55,591 was to outside consultants, 17,699 to U.S. Asian (a related party) and 17,499 shares to the members of the Board of Directors for their services. The amount expensed during the year ended December 31, 2022 in the audited consolidated statement of operations was \$270,670.

### *Warrants*

The issuance of warrants to purchase shares of the Company's common stock are summarized as follows:

	Number of Warrants	Weighted Average Exercise Price
Outstanding December 31, 2021	21,600	\$ 10.00
Issued	2,662,250	4.15
Exercised	-	-
Expired or cancelled	21,600	-
Outstanding December 31, 2022	<u>2,662,250</u>	<u>\$ 4.15</u>

The following table summarizes information about warrants to purchase shares of the Company's common stock outstanding and exercisable at December 31, 2022:

Exercise Price	Outstanding Number of Warrants	Weighted Average Remaining Life In Years	Weighted Average Exercise Price	Exercisable Number of Warrants
\$ 4.15	2,315,000	2.75	4.15	2,135,000
\$ 4.15	347,250	2.75	4.15	347,250
	<u>2,662,250</u>	<u>2.75</u>	<u>\$ 4.15</u>	<u>2,662,250</u>

The compensation expense attributed to the issuance of the warrants, if required to be recognized on the nature of the transaction, was recognized as they vested/earned. These warrants are exercisable up to three years from the date of grant. All are currently exercisable.

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## NOTE 8 — COMMITMENTS AND CONTINGENCIES

### Legal Claims

There are no material pending legal proceedings in which the Company or any of its subsidiaries is a party or in which any director, officer or affiliate of the Company, any owner of record or beneficially of more than 5% of any class of its voting securities, or security holder is a party adverse to us or has a material interest adverse to the Company other than the following:

#### Sarah Veltz v. Nexalin Technology, Inc. et al.

Plaintiff, Sarah Veltz, filed a lawsuit in this matter on January 20, 2021 in Orange County Superior Court (Case No. 30-2021-01180164-CU-WT-CJC) (the "Complaint") naming the Company and others as defendants. In her Complaint, Plaintiff contends that she was employed by defendants, including Nexalin, and has not been paid all wages, including overtime wages and other benefits allegedly due her. Plaintiff also contends that, during her employment, she was subjected to sexual harassment by the Company's then Chief Executive Officer. Plaintiff seeks both compensatory and punitive damages. On March 12, 2021, the Company filed its answer to the Complaint. Although the parties are seeking mediation, the court has set a jury trial in this matter for April 24, 2023. Management's intent is to contest the allegations vigorously and, as of the date of this report, is unable to provide an evaluation of the potential outcome of the litigation within the probable or remote range or to provide an estimate of the amount of or a range of potential loss that might be incurred by the Company.

#### Employment Development Department

The Company is currently engaged in settlement discussions with the Employment Development Department (EDD) of the state of California. This matter involves issues related to our previous management's classification of certain work provided to or on behalf of the Company's business as contract labor instead of employee labor. The total amount involved is approximately \$300,000. Management has petitioned for reassessment and believe the hired workers at issue were indeed actual contractors and not employees. We have no business in California other than one part time and one full time worker residing in California. An initial hearing before an EDD magistrate was held on April 15, 2022. A second hearing was held in June of 2022. We are now in negotiations with the EDD for a final settlement. The Company believes its potential exposure to be approximately \$300,000 and, as such, has accrued this amount on the audited consolidated balance sheets at December 31, 2022 and 2021 and believes it has adequately accrued for this matter.

#### Demand Letter from The University of Arizona

On December 8, 2022, the Company received a demand letter from the University of Arizona seeking payment of \$111,094 purportedly due on an Investigator Initiated Cooperative Study Agreement, dated as of September 25, 2017 (the "2017 Study") The Company believes that the 2017 Study was not completed and no payment was due. In fact, for a number of months prior to receipt of the demand letter, the Company had had discussions with the person at the University of Arizona who was to conduct the 2017 Study concerning updating the 2017 Study and completing an updated study and related work. After receipt of the demand letter, the Company has had discussions with the University of Arizona concerning resuming an updated study and receipt of credit for some or all the monies claimed to be due for the 2017 Study. Such discussions are ongoing, and no resolution has been reached but the Company hopes to achieve a consensual resolution.

## NOTE 9 — LEASES

With the adoption of ASC 842, operating lease agreements are required to be recognized on the balance sheet as ROU assets and corresponding lease liabilities.

On January 1, 2022, the Company exercised its right to lease an additional 400 square feet of office space and an increase of monthly rent of \$500. In accordance with ASC 842 management accounted for this as a separate lease and, as a result, recorded an ROU asset and lease liability of \$11,359.

When measuring lease liabilities for leases that were classified as operating leases, the Company discounted lease payments using its estimated incremental borrowing rate at January 1, 2022. The weighted average incremental borrowing rate applied was 9%.

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The following table presents net lease cost and other supplemental lease information:

	For the Year Ended December 31,	
	2022	2021
<b>Lease cost</b>		
Operating lease cost (cost resulting from lease payments)	\$ 54,000	\$ 48,000
<b>Net lease cost</b>	<b>\$ 54,000</b>	<b>\$ 48,000</b>
Operating lease – operating cash flows (fixed payments)	\$ 54,000	\$ 48,000
Operating lease – operating cash flows (liability reduction)	\$ 46,033	\$ 36,973

Operating leases are included in the audited consolidated balance sheets as follows:

	Classification	As of December 31,	
		2022	2021
<b>Lease assets</b>			
Operating lease cost ROU assets	Assets	6,171	-
<b>Total lease assets</b>		<b>\$ 6,171</b>	<b>\$ -</b>
<b>Lease liabilities</b>			
Operating lease liabilities, current	Current Liabilities	\$ 50,797	\$ 40,845
Operating lease liabilities, non-current	Liabilities	4,463	49,089
<b>Total lease liabilities</b>		<b>\$ 55,260</b>	<b>\$ 89,934</b>
<b>Cash Flow - Lease impact</b>			
Lease Liability		\$ 46,033	\$ 36,973
<b>Total lease liability</b>		<b>\$ 46,033</b>	<b>\$ 36,973</b>

Future minimum payments under non-cancellable leases for operating leases for the remaining terms of the leases following the year ended December 31, 2022:

Fiscal Year	Operating Leases
2023	\$ 53,675
2024	4,496
Total future minimum lease payments	58,171
Amount representing increase	2,911
Present value of net future minimum lease payments	<b>\$ 55,260</b>

Additional information related to leases is presented as follows:

	Years Ended December 31,	
	2022	2021
<b>Leases</b>		
Weighted average remaining lease term	1	2
Weighted average discount rate	9.9%	10.0%

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#### NOTE 10 — CONCENTRATION OF CREDIT RISK

##### Revenues

	Years Ended December 31,	
	2022	2021
Customer A – related party	90%	18%
Customer B	-	12%
Customer C	-	11%

No amounts under "Customer B or Customer C" listed above represented greater than 10% of revenue in 2022.

##### Accounts Receivable

Four customers accounted for 84% of accounts receivable at December 31, 2022.

Customer A	29%
Customer B	20%
Customer C	20%
Customer D	15%

Three customers accounted for 67% of the accounts receivable as of December 31, 2021, as set forth below:

Customer A	37%
Customer B	18%
Customer C	12%

**NOTE 11 — INCOME TAXES**

The Company identified their federal and Nevada state tax returns as their "major" tax jurisdictions. The periods for income tax returns that are subject to examination for these jurisdictions is 2018 through 2022. The Company believes their income tax filing positions and deductions will be sustained on audit, and they do not anticipate any adjustments that would result in a material change to their financial position. Therefore, no liabilities for uncertain tax positions have been recorded.

At December 31, 2022, the Company had approximately \$15 million in net operating loss carry-forwards for federal and state income tax reporting (tax effected) purposes. As a result of the Tax Cuts Job Act 2017 (the "Act"), certain future carry-forwards do not expire. The Company has not performed a formal analysis, but believes its ability to use such net operating losses and tax credit carry-forwards in the future is subject to annual limitations due to change of control provisions under Sections 382 and 383 of the Internal Revenue Code, which will significantly impact its ability to realize these deferred tax assets.

The Company's net deferred tax assets, liabilities and valuation allowance as of December 31, 2022 and 2021 are summarized as follows:

	Year Ended December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	\$ 3,256,000	\$ 2,960,000
R&D Costs	97,000	-
Stock-based compensation	23,000	-
Total deferred tax assets	3,342,000	2,960,000
Valuation allowance	(3,342,000)	(2,960,000)
Net deferred tax assets	\$ -	\$ -

We recorded a valuation allowance in the full amount of our net deferred tax assets since realization of such tax benefits has been determined by our management to be less likely than not. The valuation allowance increased \$416,000 and \$1,951,000 during the years ended December 31, 2022 and 2021, respectively.

A reconciliation of the statutory federal income tax benefit to actual tax benefit for the years ended December 31, 2022 and 2021 is as follows:

	2022	2021
Federal statutory blended income tax rates	(21)%	(21)%
State statutory income tax rate, net of federal benefit	(-)	(-)
Stock-based compensation	-	(15)
Change in valuation allowance	25	32
Other	(4)	4
Effective tax rate	-%	-%

As of the date of this filing, the Company has not filed its 2022 federal and state corporate income tax returns. The Company expects to file these documents as soon as practicable.

**NOTE 12 — SUBSEQUENT EVENTS**

There have been no subsequent events between the end of the period, December 31, 2022 and the filing date, March 24, 2023.

**CERTIFICATION PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002  
(18 U.S.C. SECTION 1350)**

I, Mark White, certify that:

1. I have reviewed this quarterly report on Form 10-K of Nexalin Technology, Inc.:
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 24, 2023

NEXALIN TECHNOLOGY, INC.

By: */s/ Mark White*  
Mark White  
Chief Executive Officer  
Principal Executive Officer

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**CERTIFICATION PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002  
(18 U.S.C. SECTION 1350)**

I, Marilyn Elson, certify that:

1. I have reviewed this quarterly report on Form 10-K of Nexalin Technology, Inc.:
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 24, 2023

NEXALIN TECHNOLOGY, INC.

By: /s/ Marilyn Elson  
Marilyn Elson  
Chief Financial Officer  
Principal Financial and Accounting Officer

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**CERTIFICATIONS OF THE CHIEF EXECUTIVE OFFICER  
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

The undersigned hereby certifies, in accordance with 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, in his capacity as an officer of NEXALIN TECHNOLOGY, INC., that, to his or her knowledge, the Quarterly Report of Nexalin Technology, Inc. on Form 10-K for the period ended December 31, 2022 fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934 and that the information contained in such report fairly presents, in all material respects, the financial condition and results of operation of the company.

A signed original of this written statement required by Section 906 has been provided to NEXALIN TECHNOLOGY, INC and will be retained by NEXALIN TECHNOLOGY, INC and furnished to the Securities and Exchange Commission or its staff upon request.

March 24, 2023

NEXALIN TECHNOLOGY, INC.

By: */s/ Mark White*  
Mark White  
Chief Executive Officer  
Principal Executive Officer

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**CERTIFICATIONS OF THE CHIEF FINANCIAL OFFICER  
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

The undersigned hereby certifies, in accordance with 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, in his capacity as an officer of NEXALIN TECHNOLOGY, INC., that, to his or her knowledge, the Quarterly Report of Nexalin Technology, Inc. on Form 10-K for the period ended December 31, 2022 fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934 and that the information contained in such report fairly presents, in all material respects, the financial condition and results of operation of the company.

A signed original of this written statement required by Section 906 has been provided to NEXALIN TECHNOLOGY, INC and will be retained by NEXALIN TECHNOLOGY, INC and furnished to the Securities and Exchange Commission or its staff upon request.

March 24, 2023

NEXALIN TECHNOLOGY, INC.

By: /s/ Marilyn Elson

Marilyn Elson

Chief Financial Officer

Principal Financial and Accounting Officer

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