Risk Factors Comparison 2024-03-27 to 2023-03-27 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

Risks ~~Relatedly, -~~ **Related** ~~, the spread of~~ **to Our Financial Position** ~~an~~ **and** ~~infectious disease~~ **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 ~~COVID~~ **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, 2023, we incurred a comprehensive loss in the amount of $ 4, 685, 427. Our accumulated deficit at December 31, 2023, was $ 77, 038, 049. 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 regulatory authorities require us 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. We may not be able to continue as a going concern if we do not execute our business plan or obtain additional financing in the future if necessary. Our independent accountant' s audit report included on this Form 10 - ~~19~~ K filed states that there is substantial doubt about our ability to continue as a going concern. We have incurred only losses since our inception , raising substantial doubt about our ability to continue as a going concern. Therefore, our ability to continue as a going concern is highly dependent upon us executing our business plan in the planned amount of time allotted or obtaining additional financing for our planned operations if necessary. There can be no assurance that we will be able to raise any additional funds, or if we are able to raise additional funds, that such funds will be in the amounts required or on terms favorable to us. Our limited operating history** may ~~also~~ **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 ~~in~~ **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 as yet been approved by the FDA for marketing or sales in the United States. Consequently, any predictions you make about our future success or** ~~inability~~ **viability** ~~of~~ **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** ~~our~~ **or** ~~suppliers to deliver components~~ **unknown factors in achieving** ~~or our raw materials on a timely basis. Such events may result in a period of~~ business **objectives. We will need to transition at some point from a company with a research** and **development focus to a company capable** ~~manufacturing disruption, and in reduced operations, any~~ of ~~which could materially affect~~ **supporting commercial activities. We may not be successful in such a transition. We expect** our ~~business,~~ 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 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 $ 4, 685, 427 for the year ended December 31, 2023. We may need to obtain substantial additional funding in connection with our continuing operations **and planned activities . Our future capital requirements** ~~The extent to which the coronavirus impacts our business~~ 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; ● 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** ~~developments~~ **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 ~~highly uncertain and~~ **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; ● 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 ~~predicted~~ **subject to reclassification by the FDA ,** ~~including~~ **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 ~~information which may emerge concerning~~ **ruling that separated anxiety and insomnia from** the ~~severity~~ **treatment** of ~~COVID~~ **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** ~~19 and the actions to contain the coronavirus or~~ **for** ~~treat its~~ **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** , ~~among~~ **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. We plan to conduct decentralized clinical trials for the Gen- 3 device in the U. S. and have consulted the FDA as part of the pre- submission meetings. 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 enrolment 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** ~~others~~ **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** . 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~~ **will** 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. 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; ● 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~~ **2023**, 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. 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,~~ **The global tensions resulting from the** Russia ~~- launched an invasion in~~ Ukraine ~~which has~~ **conflict and the conflict in Israel and the Gaza Strip have** 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 **are** ~~expect to conduct~~ **conducting** ~~a material portion of~~ our research in China through the ~~potential~~ Joint Venture. Also, the ~~potential~~ Joint Venture **was** ~~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. 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 **China' s State Administration of Foreign Exchange (** 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. Fluctuation in exchange rates could have a negative effect on our results of operations and the value of ~~your~~ **an** investment **in the Company** . 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 **of this** 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 **hedge our exposure** 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~~ **variable interest entity** structures and whether the ~~VIE~~ **variable interest entity** 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. Risks Related to Our Intellectual Property 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~~ **(the “** 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~~ **and Gen- 3** ~~device~~ **devices** ~~has~~ **have** completed development and ~~is~~ **are** 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 whistle blower 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 program 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 **purchase** ~~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~~ **There** can be no assurance that there will be an increase in the trading our of securities. as a result, investors may be required to hold our securities for a longer period than originally contemplated **. If we are not able to comply with the applicable continued listing requirements or standards of The Nasdaq Stock Market, Nasdaq could delist our common stock. Our common stock is currently listed on The Nasdaq Stock Market. In order to maintain that listing, we must satisfy minimum financial and other continued listing requirements and standards, including the Minimum Bid Price Rule (as discussed below) and those regarding director independence and independent committee requirements, minimum stockholders' equity, and certain corporate governance requirements. There can be no assurances that we will be able to comply with the applicable listing standards. We are required to maintain a minimum bid price of $ 1. 00 per share. On May 10, 2023, the Company received written notice from The Nasdaq Stock Market LLC (" Nasdaq ") notifying the Company that it was no longer in compliance with the minimum bid price requirement for continued listing on Nasdaq, as the closing bid price for the Company' s common stock was below $ 1. 00 per share as set forth in the Nasdaq listing rules. The Company was afforded 180 calendar days, or until November 6, 2023, to regain compliance with the Nasdaq listing rules. The Company was unable to regain compliance with the bid price requirement by November 6, 2023. On November 7, 2023, the Company submitted a letter to NASDAQ requesting a second 180- day period in order to regain compliance with NASDAQ Rule 5550 (a) (2). The Company stated in that letter that it believed it will be able to cure the deficiency and increase its stock price to above $ 1. 00 per share pursuant to its plan to do so. On November 7, 2023, the Company received written notice from the Nasdaq Listing Qualifications Department (the " Staff ") that the Company was not eligible for an additional 180 calendar day compliance period because the Company no longer complied with Nasdaq' s $ 5 million minimum stockholders equity initial listing requirement. On March 6, 2024, the Nasdaq Hearing Panel granted the Company a temporary exception to regain compliance with the Minimum Bid Price Rule until April 25, 2024** . 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~~ **initial public offering** (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~~ **holders** , thereby making ~~your~~ **such** 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~~ **holders** (i) to exercise ~~your~~ **their**

warrants and pay the exercise price therefor at a time when it may be disadvantageous for ~~you~~ **them** to do so, (ii) to sell ~~your~~ **their** warrants at the then- current market price when ~~you~~ **they** might otherwise wish to hold ~~your~~ **their** 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~~ **their** warrants. Holders of the ~~Warrants~~ **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~~ **warrants**, which could limit the ability of ~~Warrant~~ **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~~ **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~~ **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~~ **warrant** holder in any such enforcement action by service upon such ~~Warrant~~ **warrant** holder' s counsel in the foreign action as agent for such ~~Warrant~~ **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~~ **were** 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~~ **As of March 20, 2023, the expiration of the 180- day lock- up period after the public 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~~ **are now eligible** for **future** 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~~ **27** . ~~38~~ **93** % of our outstanding common stock, based on the number of shares of our common stock outstanding as of March 22, ~~2023~~ **2024** . 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~~ **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~~ **affected** 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~~ **initial public offering** . 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~~ **We have identified certain material weaknesses in our** internal controls, **which could impair** 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. **As required by Section 404 of the Sarbanes- Oxley Act** ~~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~~ **each fiscal** year ~~, as required by Section 404 of the Sarbanes- Oxley Act~~ . This ~~will require~~ **requires** ~~that we~~ **us to** 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~~ **As of the fiscal year ended December 31, 2023,** our ~~internal~~ **management evaluated, with the participation of our chief executive officer and chief financial officer, the effectiveness of our disclosure** controls ~~within a specified period,~~ and **procedures** , ~~as a result, we may experience difficulty in meeting~~ **pursuant to Rule 13a- 15 (b) under** ~~these~~ -- **the Exchange Act** ~~reporting requirements in a timely manner~~ . **Based upon** ~~We identified control deficiencies in the design and operation of our internal control over financial reporting~~ that ~~constituted a~~ **evaluation, our management concluded that our disclosure controls and procedures were not effective due to the following** material ~~weakness~~ **weaknesses** ~~, 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 **the** ~~documentation of~~ review ~~/ approval~~ of ~~journal entries and~~ reconciliations **and the accounting for the Company' s stock options that were granted in the current year** ; 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 **an** 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~~